

AR226-1867



8EHQ-0904-00373

DuPont Haskell Laboratory
for Health and Environmental Sciences
Elkton Road, P.O. Box 50
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September 17, 2004

Via Federal Express

8EHQ-80-373

32pp.

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20460

CONTAINS NO CBI

Dear 8(e) Coordinator:

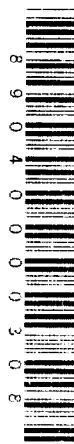
Ammonium Perfluorooctanoate
8EHQ-0381-0394

This letter is submitted "For Your Information" to supplement the letter of September 7, 2004 submitted by Mr. Edward E. Shea, representing MIC Specialty Chemicals, Inc. (Attachment I). Overall, the letter and accompanying trip report are an accurate reflection of the proceedings of the meeting held at the Inn at Montchanin Village on August 20-21, 2004. Our conclusions from the meeting are summarized as follows:

1. No effects were observed on the general health of the workers at the Miteni plant.
2. No changes in clinical chemistry parameters were observed with the exception of an apparent slight alteration of serum lipid levels that correlated with exposure. The cause and biological significance of this observation is unclear and requires further analysis.
3. Although the observed changes appear to be correlated with exposure, it does not demonstrate a causal association with exposure to these substances.
4. Average serum levels of PFOA were higher in the Miteni workers than have been reported for occupational exposure, and significantly higher than levels reported in the general population.

For the sake of completeness, we are submitting with this letter a copy of the data slides that summarize DuPont's preliminary analysis of the serum lipid data (Attachment II). We note that 3M actually led the initial analysis of the Miteni data including the 37 blood parameters mentioned in Dr. Costa's trip report. After seeing the preliminary analysis of the serum lipid data, DuPont subsequently undertook an independent statistical analysis of the serum lipid data only, and presented our preliminary analysis at the August 20-21 meeting. With respect to the data referenced in Mr. Shea's letter we note the following:

1. In Table 1 it should be noted that analyses of the sera of the "PFOA-exposed" group also revealed the presence of PFOS (perfluorooctanoic sulfonate). Dr. Costa confirmed that the plant worked with both perfluorinated compounds. The average serum PFOA concentration was ~ 16 ppm with a range of 0.04-92 ppm and for serum PFOS the average was ~ 0.5 ppm with a range of 0.06-3.3 ppm. It should be noted that no analyses for these same perfluorinated compounds was undertaken for the sera of workers in the non-PFOA/non-PFOS area ("Non-PFOA" group).



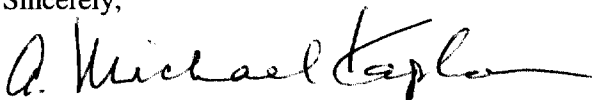
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2. There are a number of caveats that are germane to the interpretation of the data in addition to the fact that workers were exposed to both PFOA and PFOS; notably:
 - a. The dataset consists of a small and arbitrary collection of subjects (~35 employees).
 - b. There are no pre-employment/baseline lipid levels for historical reference in the study population.
 - c. Concomitant exposure to other chemicals in the plant is an unknown variable.
 - d. Serum lipids are well known to be affected by many different factors including family history, diet, and lifestyle; data on these factors were not available for inclusion for analysis.
3. There was a strong correlation observed between PFOA and PFOS levels. Therefore, we analyzed the relationship between the various serum lipids with respect to three dependent variables: total perfluorinated compound (the sum of PFOA + PFOS), PFOA alone and PFOS alone.
4. The data have been analyzed in terms of a linear model; however, other models may fit the data better. In general, there is no *a priori* reason to expect a linear dose-response relationship in a biological system.

As indicated in Mr. Shea's letter, DuPont has additional ongoing studies that may enable a broader interpretation of this small study in the Miteni workers. Notably, we are conducting a study, "Ammonium Perfluorooctanoate: Cross-Sectional Surveillance of Clinical Measures of General Health Status Related to a Serum Biomarker of Exposure and Retrospective Cohort Mortality Analyses in a Polymer Production Plant" of over 1,000 employees at our Washington Works plant. Currently we are analyzing the data and expect to issue a final report by year's end. In addition, we are evaluating the effects of perfluorinated compounds on the activation of various nuclear receptors, e.g., PPAR α , in an effort to better understand the biological activity of this class of chemicals. Finally, we are exploring the hypothesis that hyperlipidemia prolongs retention of PFOA in the serum, thus accounting for the observed correlations.

A copy of the final report(s)/manuscript(s) for the DuPont studies will be submitted to the Agency when available.

Sincerely,



A. Michael Kaplan, Ph.D.
Director – Regulatory Affairs and Occupational Health

AMK/RWR/PJG:clp
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Attachments: (I) "Mr. Edward E. Shea's TSCA Letter, September 7, 2004"
(II) "DuPont Statistical Analysis of Serum Lipid Data of Miteni Workers"

ATTACHMENT I

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September 7, 2004

TSCA Confidential Business Information Center (7407M)
EPA East - Room 1428
U.S. Environmental Protection Agency
1201 Constitution Avenue, N.W.
Washington, DC 20004-3302

Ladies and Gentlemen:


We represent MIC Specialty Chemicals, Inc. Pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA), we submit on behalf of our client a copy of a report dated August 23, 2004 to Miteni S.p.A by Dr. Giovanni Costa of the University of Verona describing a meeting with 3M and du Pont to discuss biological monitoring of Miteni workers exposed to perfluorooctanoic acid (PFOA). A Department Manager of our client received a copy of the memorandum on August 23, 2004 during an overseas trip.

Miteni is an Italian company which manufactures PFOA in Italy. Our client imports PFOA purchased from Miteni into the United States.

In general, the information described in the enclosed report appears to be favorable and our client does not know that any information in the report indicates a substantial risk. However, our client is not in a position to make that determination and, therefore, decided to make the submission on a precautionary basis. Our client advises that the enclosed information is the only information which it has about the biological monitoring described in the report.

If you have any questions, please call me at 212-237-1140.

Very truly yours,



Edward E. Shea

EES:mg

cc: Hitoshi Inada, Esq.
Takehiro Fujimura, Esq.
Ms. Marian Roach

(10282443:1)

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P.IVA 0237309 023 8

Verona, 23.08.2004

Spett.
Direzione
MITENI S.p.A.
Trissino (VI)

Report on the meeting held on Friday 20th and Saturday 21st 2004 at the Inn at Montchanin Village (Wilmington, USA) with 3M and DuPont delegations.

1. Participants:

- John Butenhoff	3M, toxicologist
- Geary Olsen	3M, clinical epidemiologist
- Larry Zobel	3M, occupational health physician
- Peter Gillies	DuPont, expert in lipid metabolism
- John Green	DuPont, statistician
- Gerald Kennedy	DuPont, toxicologist
- Robin Leonard	DuPont, epidemiologist
- Robert Rickard	DuPont, toxicologist
- Giovanni Costa	Miteni, occupational health physician

2. Background

On August 9th I have been invited by G. Olsen (3M) to participate in this meeting, organised jointly with P. Gillies (DuPont), aimed at discussing the results of the analysis of the data collected by me at Miteni plant in Trissino, concerning the workers of the PF department.

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As it was been agreed last year in the ambit of the *APME-APFO ad hoc toxicological working group*, I have started a scientific collaboration with them aimed at evaluating the data related to the periodical, biological monitoring of Miteni workers exposed to PFOA.

Despite the small number of workers involved (compared to 3M and DuPont workers), such data were considered very helpful in understanding any possible interaction of PFOA with human physiology, as such cohort of workers has been checked regularly since 1979 by annual medical examinations, integrated by several blood and urine analysis. In the case of 3M workers, some workers (on voluntary basis) have been checked occasionally (1993, 1996, 2000), whereas DuPont did not carry out regular checks of such kind in the past, but it is now carrying on a general examination of more than 400 workers, the results of which are due by the end of this year.

Therefore, the statistical analysis of Miteni data was considered very useful for checking whether or not any pre-clinical adverse effect could be detected, in order to better address the checks of larger groups at 3M and DuPont plants, and for further more detailed investigations on some specific biological parameters.

So, in December 2003 (after discussion and agreement with Miteni general management in the meeting held in Frankfurt on November 21st) I sent G. Olsen the first database of the biological monitoring of Miteni workers (in anonymous format) and, in February 2004, on occasion of the SOT Conference held in Baltimore, I had a first meeting with them and other 3M and DuPont experts (see my report dated 29.03.04 and abstract below) for a preliminary analysis of the data.

Thereafter, we decided to integrate the dataset with some more specific analysis concerning the lipids metabolism, that I collected during the periodical, annual blood check carried out in Spring this year.

Consequently, two months ago I sent G. Olsen and P. Gillies two updated datasets (still in anonymous format), one concerning the biological data available since 1987 of all exposed workers to PFOA, and the second one concerning the last blood analysis carried out in Spring 2004.

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3. Preliminary results of the statistical analysis

The analysis of the first database was aimed at evaluating any possible abnormality of biological parameters, occurred in the last 17 years, in relation to the PFOA blood levels measured in the last 4 years (2000-2003); the second one was aimed at comparing exposed and non-exposed workers to find out any difference that could be statistically associated to PFOA exposure.

The statistical analysis, carried out by means of appropriate statistical programs by DuPont expert statisticians, confirmed the negative results for almost all the 37 blood parameters considered: in particular no significant effects were detected as concerns haematology, proteins metabolism, immunology, liver, kidney and prostate function.

Only some slight effects on lipids metabolism were detected, which deserve further analysis and proper interpretations.

In fact, a slight increase of total cholesterol in workers exposed to PFOA was observed, which also appeared to show an increasing trend associated with the highest blood PFOA levels.

Table 1 shows the comparison of exposed and non-exposed workers and the slight significant increase of total cholesterol in exposed workers. There is no increase of other lipids, such as tryglicerides in particular, but the fraction of "Non-HDL Cholesterol" seems that concerned.

Figure 1 shows the positive correlation between total cholesterol and PFOA blood levels in the last 4 years (when PFOA was measured): a slight association between PFOA blood level and total cholesterol concentration seems to be consistent over the years. Figure 2 shows the same trend as concerns "Non-HDL Cholesterol".

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Table 1: Comparison of the main lipid components in exposed and non-exposed workers to PFOA

Endpoint	Manufacturing Area		P-value
	Non-PFOA	PFOA	
Serum Lipids			
Total Cholesterol	214 ± 4	233 ± 9	0.03
HDL Cholesterol	53 ± 1	51 ± 2	0.37
LDL Cholesterol	133 ± 3	146 ± 8	0.09
Non-HDL Cholesterol	160 ± 4	182 ± 10	0.03
Non-HDL/HDL	3.3 ± 0.2	3.9 ± 0.3	0.09
Total Triglycerides	141 ± 12	169 ± 19	0.22
Demographic Characteristics			
Age	39.5 ± 1.0	40.7 ± 1.5	0.53
BMI	25.3 ± 0.3	25.7 ± 0.5	0.52
Alcohol Consumption	0.27 ± 0.02	0.36 ± 0.04	0.07

Values are expressed as the mean ± SEM for approximately n = 94 non-PFOA workers and n = 35 PFOA workers.

Data are from a 2004 sample collection

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Figure 1: Correlations between Total Cholesterol (log) and PFOA (log) levels in the 4 years

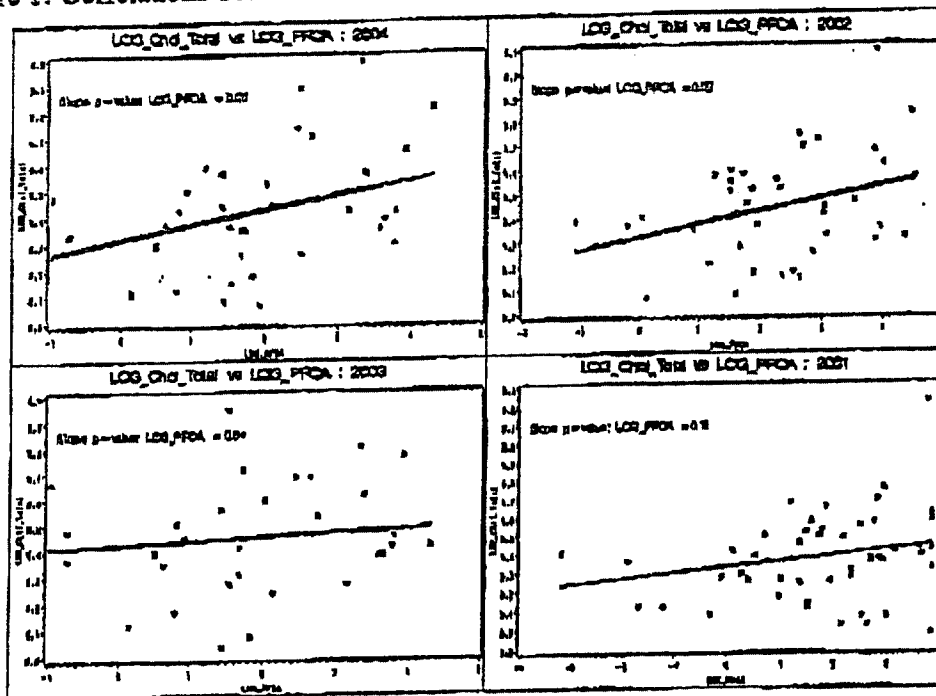
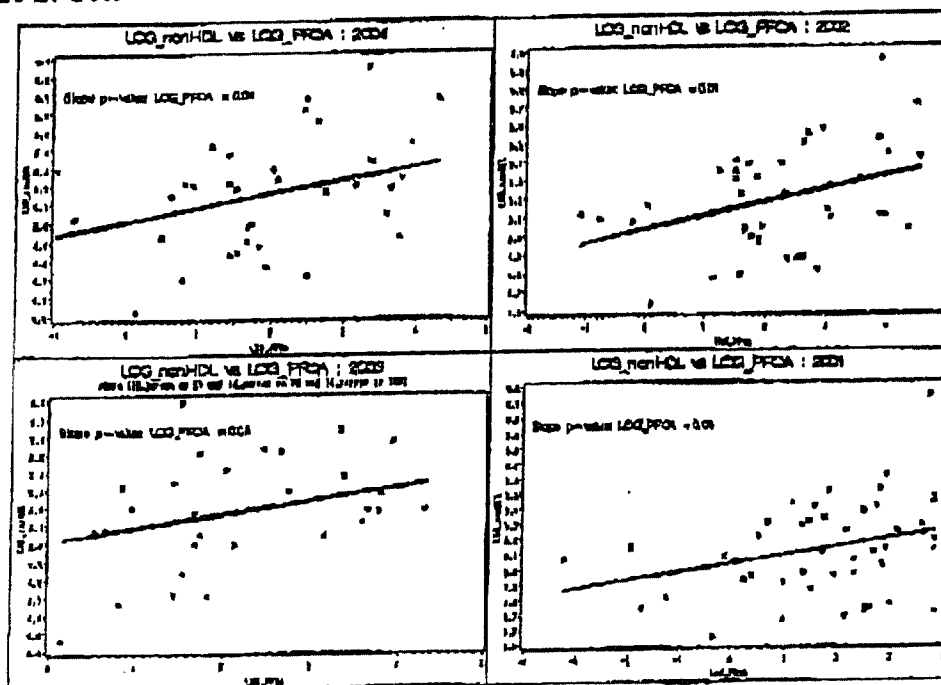


Figure 2: Correlations between non-HDL Cholesterol (log) and PFOA (log) levels in the 4 years



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In the light of these findings, G. Olsen (3M epidemiologist) reviewed the 3M datasets related to their surveys carried out in 1993, 1996 and 2000, and a preliminary analysis concerning cholesterol levels appears to be in agreement with the Miteni data.

In other words, it seems that PFOA (probably only at high blood concentrations) can interfere with metabolism of Cholesterol, in particular by increasing the fraction of "Non-HDL Cholesterol".

Such findings need a precise interpretation, also because they are in contrast with the animal experimental data (rats), where PFOA causes a decrease of cholesterol levels. That can be related to interspecies differences in drug metabolism, which are also raised for the different findings in carcinogenicity (it is carcinogen in rats, but not in primates and humans).

In order to elucidate better the possible mechanisms underlying such effect P. Gillies, DuPont expert on lipid metabolism, made an updated review of the current knowledge on lipids metabolism, trying to make some hypothesis about possible mechanisms. According to his analysis, such effect cannot be mediated by a PPAR α mechanism (as suggested for rats), but it is probably due to an interference with a protein (CEPT) able to transfer of cholesterol in blood and liver. He is going to have a deeper insight on such matter both by further discussion with the best academy experts on lipids and by a bio-molecular study concerning the nuclear receptors for such protein.

4. Communication and regulatory aspects.

Robert Rickard (DuPont) said that is going to have a FYI ("For your information") meeting with EPA next Wednesday, August 25th.

According to the TSCA 8e rules he has to report to EPA any new data concerning possible toxicological characteristics of PFOA DuPont may know, with particular reference to human health.

He exposed his agenda, which includes an updating of the recent toxicological studies carried out at the Haskell Lab concerning the exposure of rats and mice to linear, branched

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and mixed (linear/branched) PFOA, as well as the presentation of some ongoing studies, dealing with the health examination of more the 400 workers at DuPont "Washington" plant in West Virginia, and the review of epidemiological data concerning mortality in general population of West Virginia. G. Olsen and L. Zobel (3M) will also communicate their epidemiological data concerning 3M workers at Decatur and Antwerp plants.

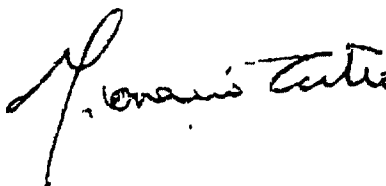
In such agenda he would like to mention also some findings related to the data on lipid metabolism mentioned above, related to Miteni workers, keeping anonymous the source of data. In particular, he would like to report the positive findings of a long lasting medical surveillance of workers exposed to PFOA, showing no effects on general health and also on biological parameters, concerning the main target organs and functions, except for a mild possible interference with lipid metabolism, which deserves further analysis.

So, he asked me whether he can report such data, in particular he would like to show one or two charts related to the lipid parameters (such as figures 1 and 2) in his presentation, without mentioning the source and the name of Miteni, and without giving EPA any written document.

As I replied that I could not deal with such request, but he must ask and get the formal permission from Miteni Management, due to the short time available he asked me to pass you such request in order to get your response (whatever it is) as soon as possible.

With kind regards

Prof. Giovanni Costa



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Abstract of my report dated 29.03.04 concerning the meeting of the APME-APFO ad hoc toxicology groupo, held in Baltimore on March 24.03.04.

5.2. Workers.

The Chairman noted that most of the companies represented in the WG had commenced or were about to embark on a blood level monitoring programme in their current employees (Asahi Glass has just started it and asked me some advice concerning the parameters to be collected from the workers). He encouraged all companies to share their data in the way that Miteni and 3M had done in the past, and he also asked me to co-ordinate the outcomes for the APME group; I gave him my willingness for that.

As also Asahi Glass is sending its sample to the German lab already used by Solvay, I suggested that all European should join this lab, provided that it is quite reliable, in order to limit the factors that can confound the results.

As concerns our data, I informed the group that we analysing them with reference to the interaction with lipid metabolism in collaboration with Geary Olsen (3M) and Peter Gillies (DuPont); see the enclosed report of the meeting held at Marriott hotel on Wednesday morning with G. Olsen and J. Butenoff (3M) and P. Gillies and G. Kennedy (DuPont).

G. Kennedy confirmed that DuPont is starting its biomonitoring according to the protocol he circulated to the group in the last week. On Wednesday evening I have been invited for a dinner by Larry Jansen (Lawyer) and Robert Rickard (Science Director) of DuPont for exchanging information about the workers' biomonitoring (see attached report).

Attachment 1.

Meeting with G. Olsen and J. Butenhoff (3M toxicologists), Peter Gillies and J. Kennedy (DuPont toxicologists)

On Wednesday 24th morning, I had a 3-hour meeting with with 3M and DuPont toxicologist to discuss the preliminary findings of the data collected in MITENI workers and concerning the possible interference of PFOA with lipid metabolism.

G. Olsen have carried out a preliminary statistical analysis of the biochemical data related to year 2002 and 2003, which showed some possible slight effects on HDL and LDL cholesterol.

P. Gillies (DuPont expert on lipids) described the meaning of the different blood lipid components and their possible interaction with PFOA.

After a long discussion and a careful analysis of the present data, it has been convened to add further data to the dataset, in particular those related to the ongoing biomonitoring which is due to end by April. In this survey further analysis of lipids and proteins (LDL.Cholesterol, APO-A2, APO-B, reactive C-protein) have been added in order to clarify better such interaction.

So, I agreed in sending them such new data by the end of April and then start a deeper statistical analysis.

The results are expected to be sent to a toxicology journal for publication by the end of the year.

Attachment II

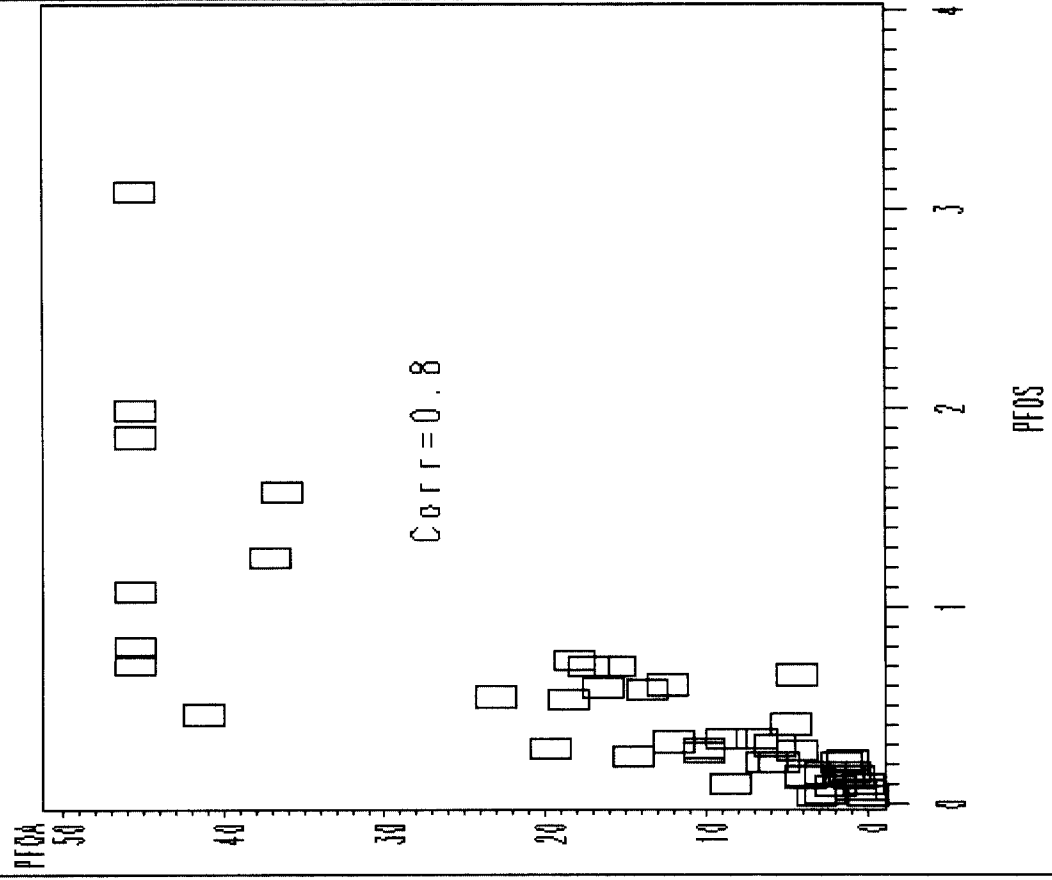
DuPont Statistical Analysis

of Serum Lipid Data

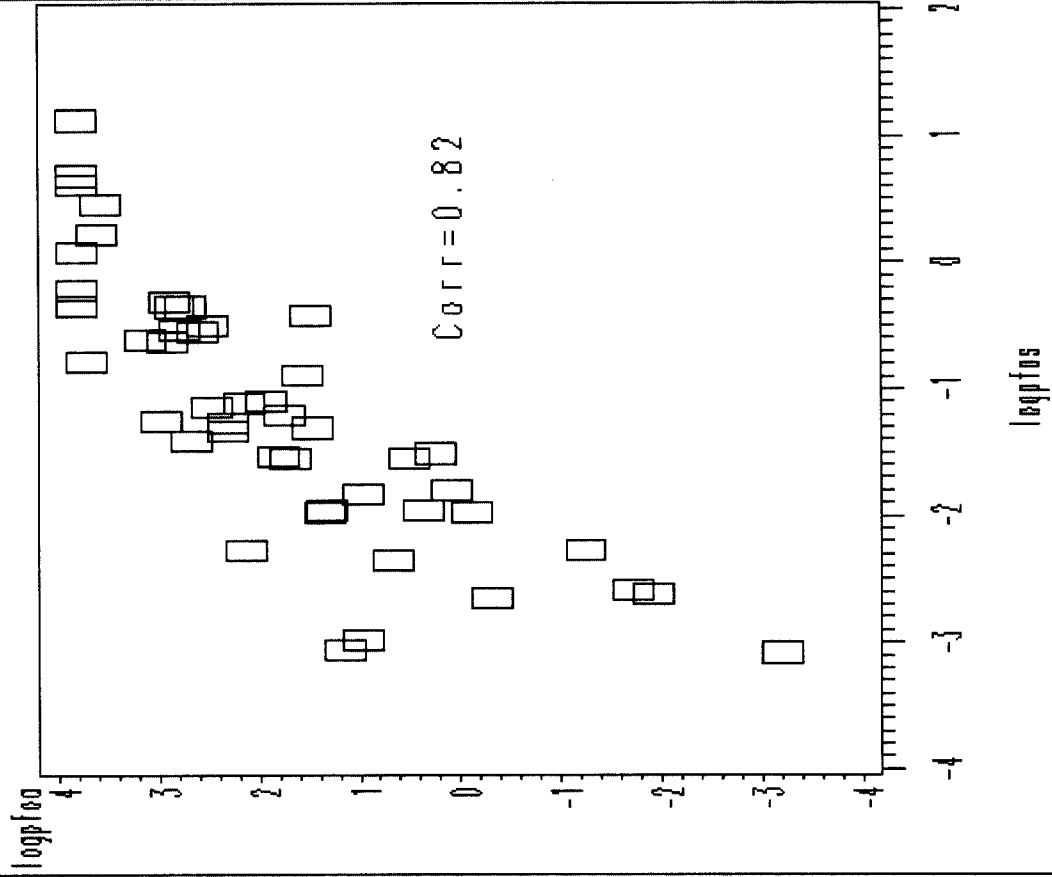
of Miteni Workers

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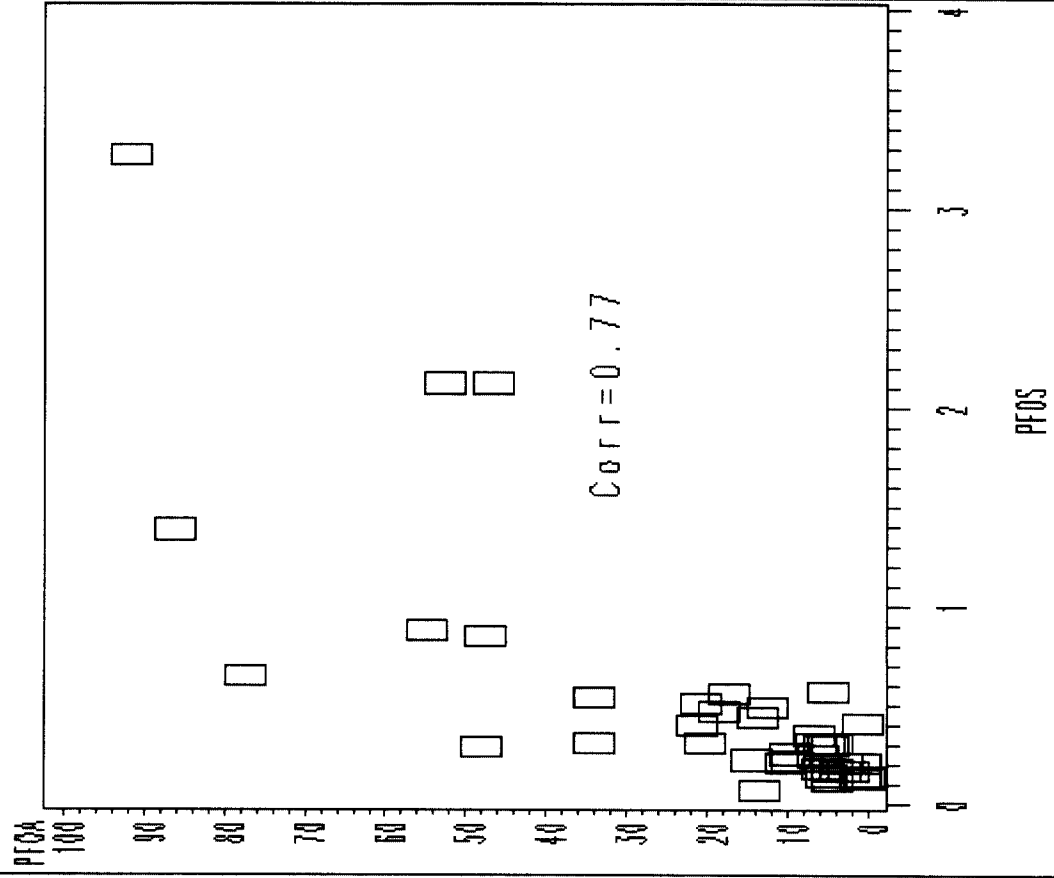
PFOA vs PFOS in 2001



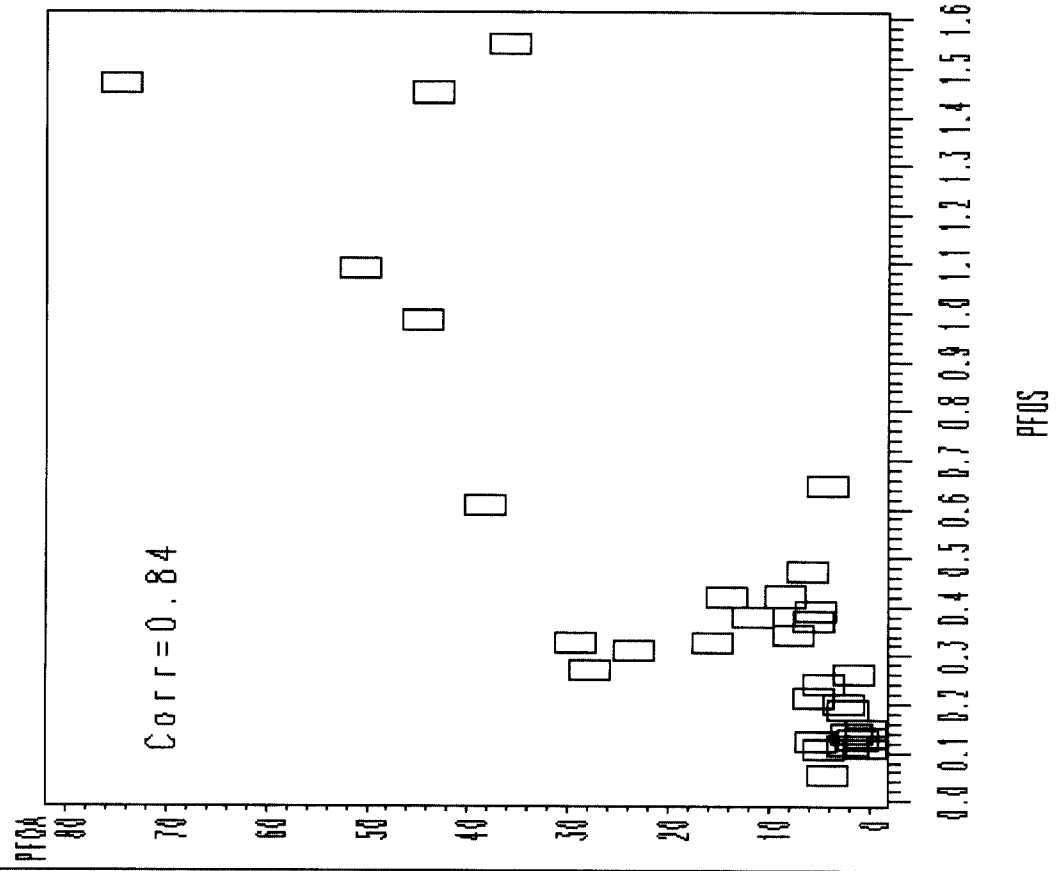
LOGPFOA vs LOGPFOS in 2001



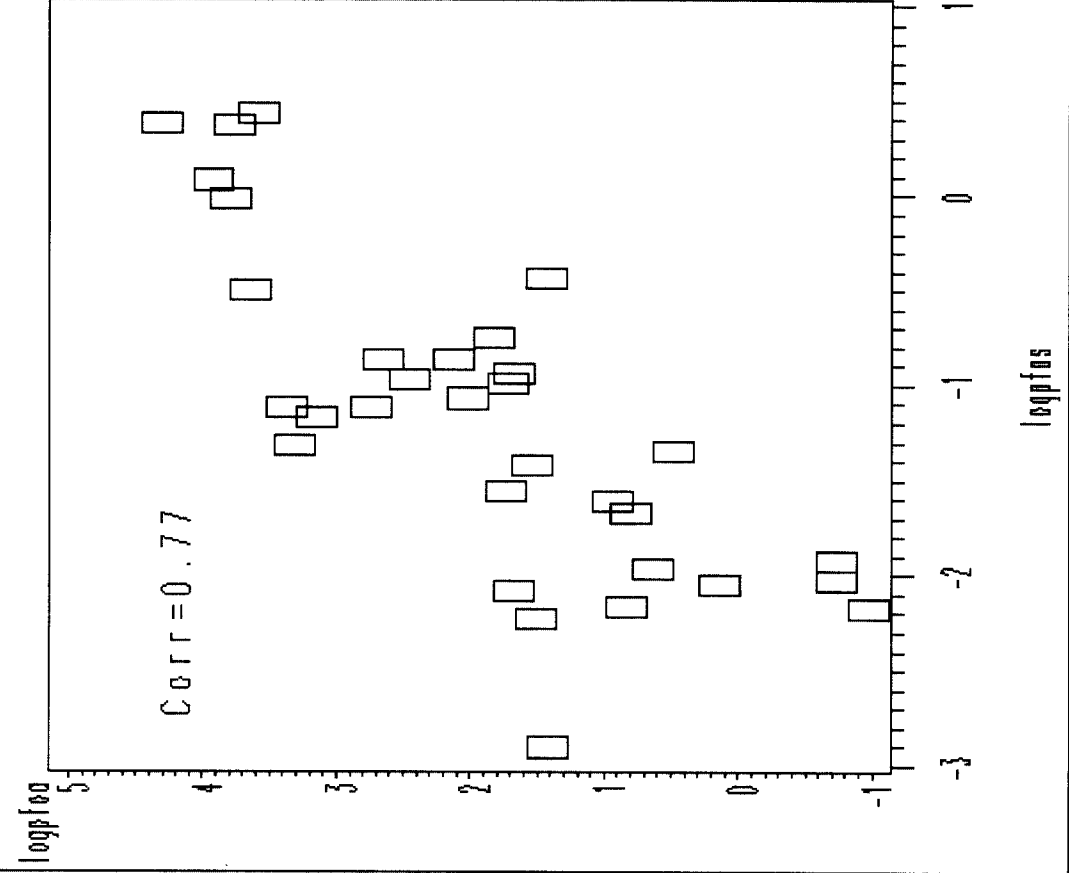
PFOA vs PFOS in 2002



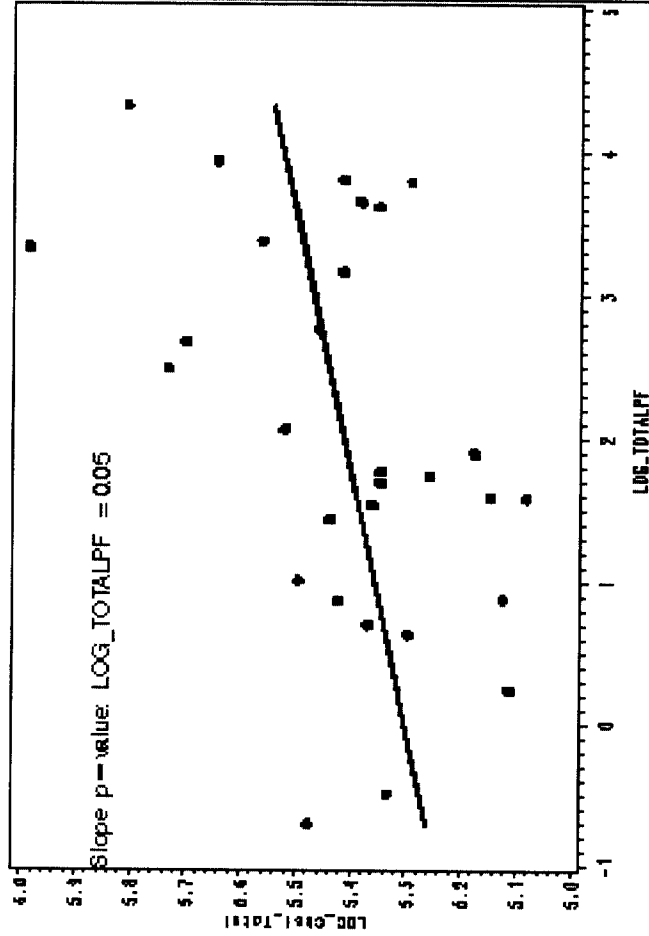
PFOA vs PFOS in 2003



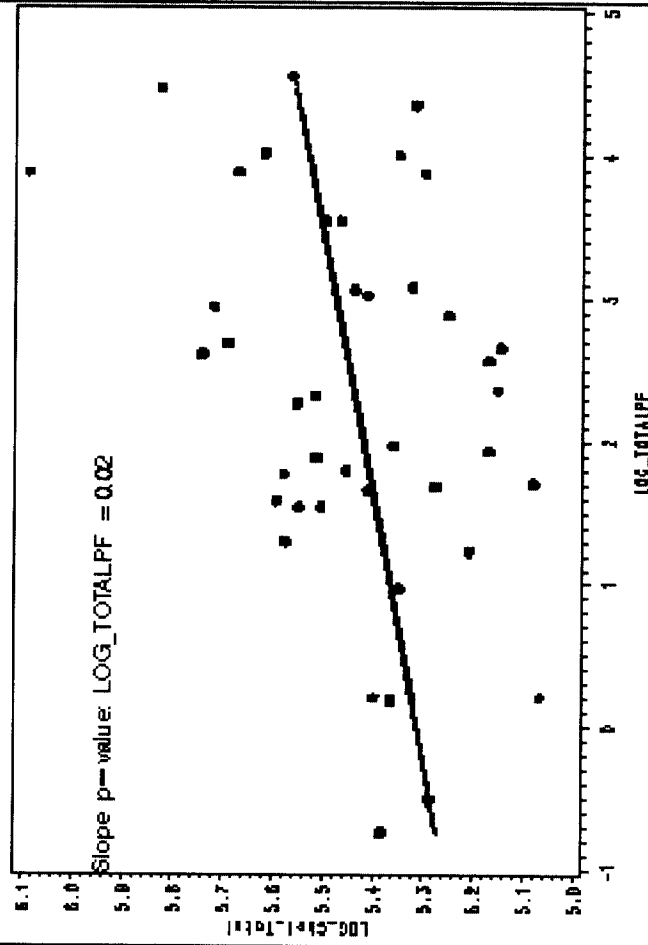
LOGPFOA vs LOGPFOS in 2003



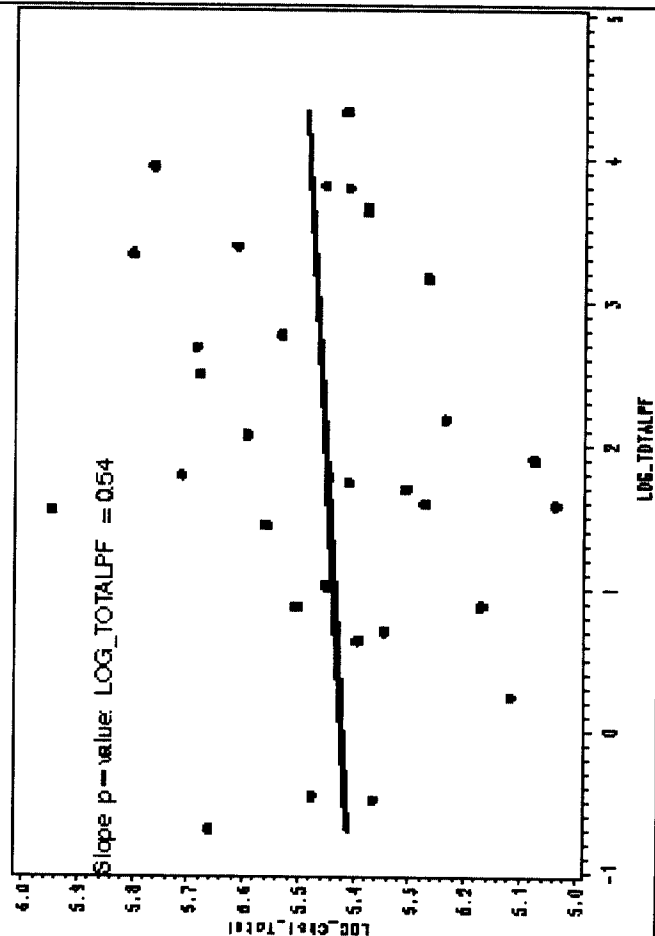
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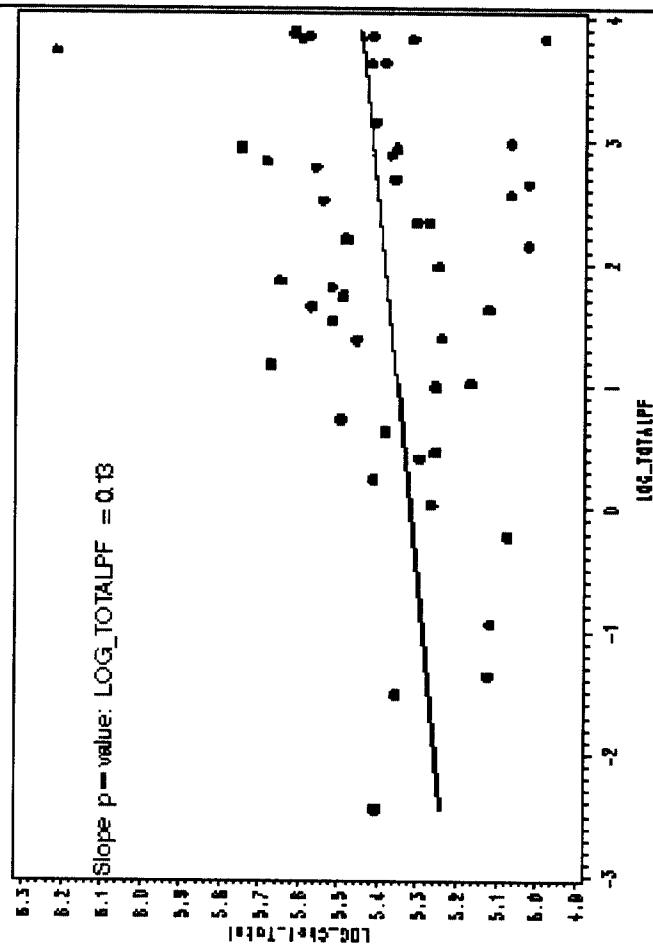
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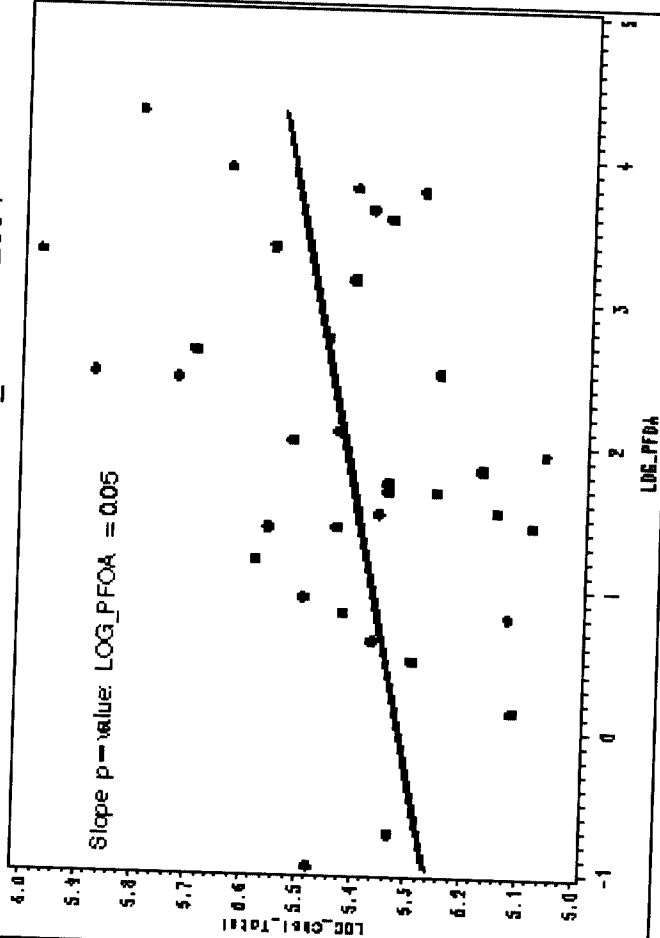
LOG_Chol_Total vs LOG_TOTALPF : 2003



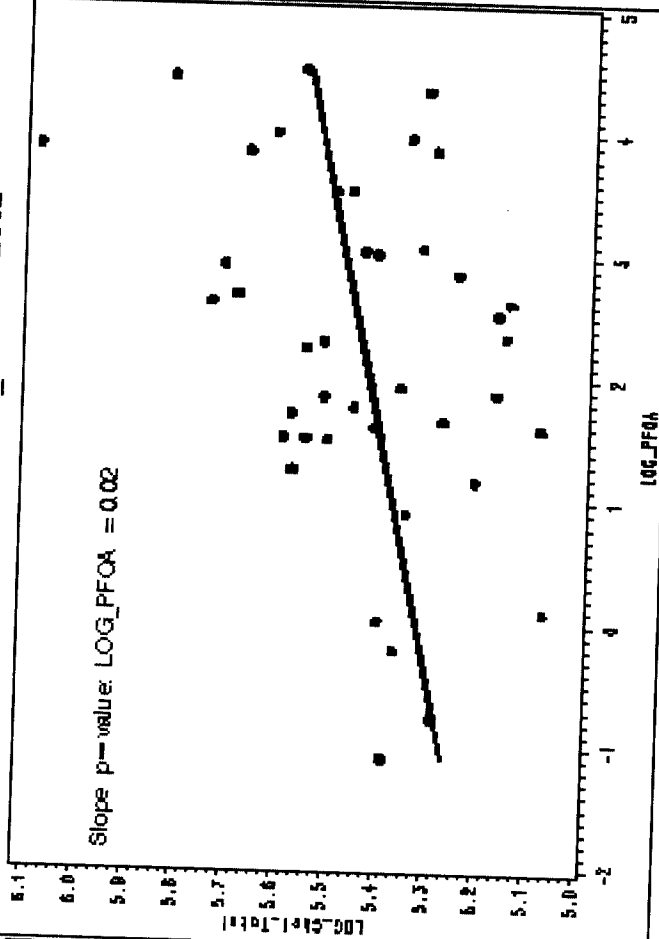
LOG_Chol_Total vs LOG_TOTALPF : 2001



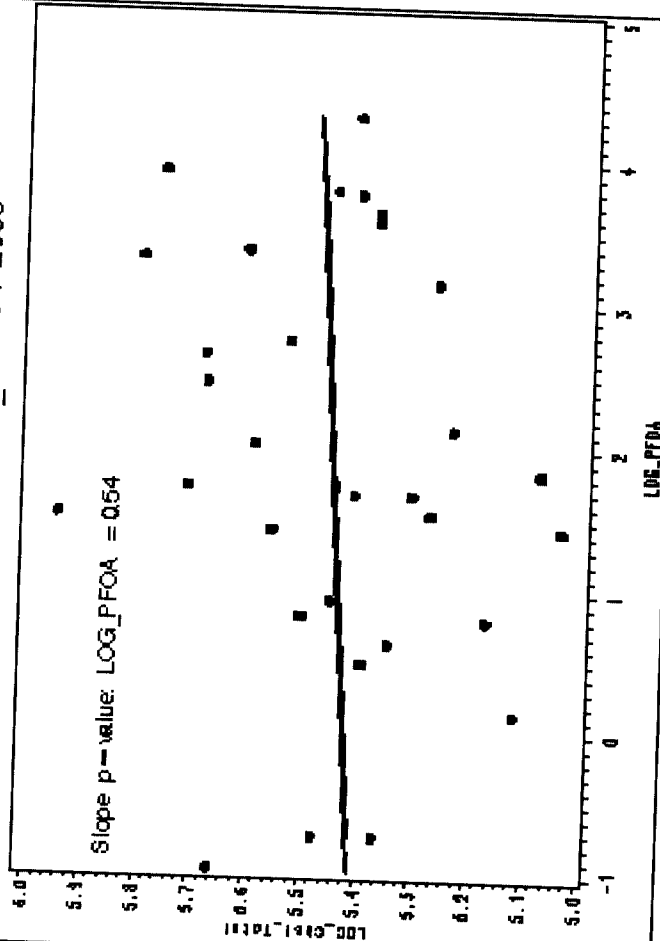
LOG_Chol_Total vs LOG_PFOA : 2004



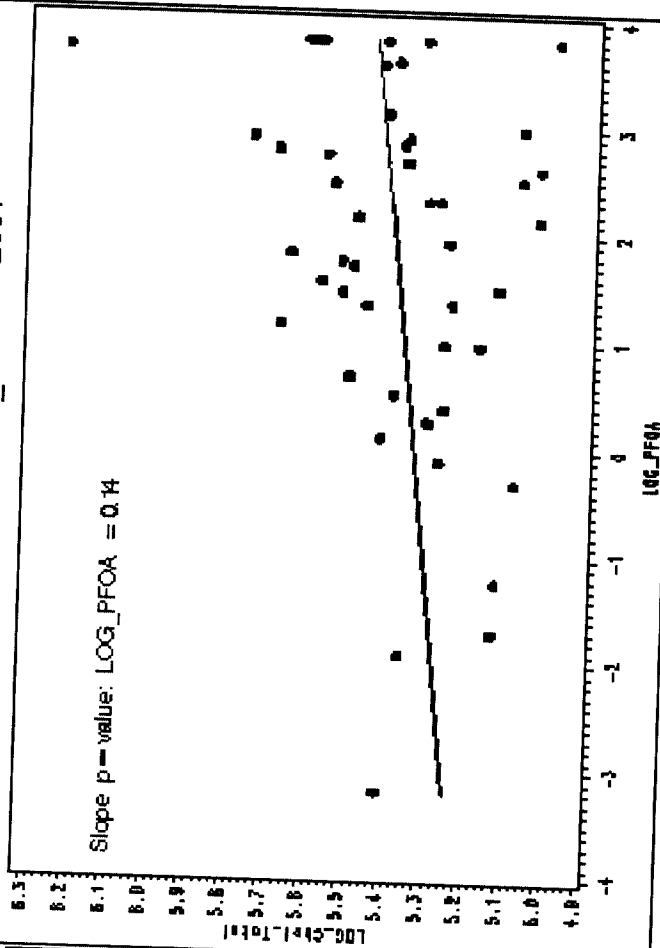
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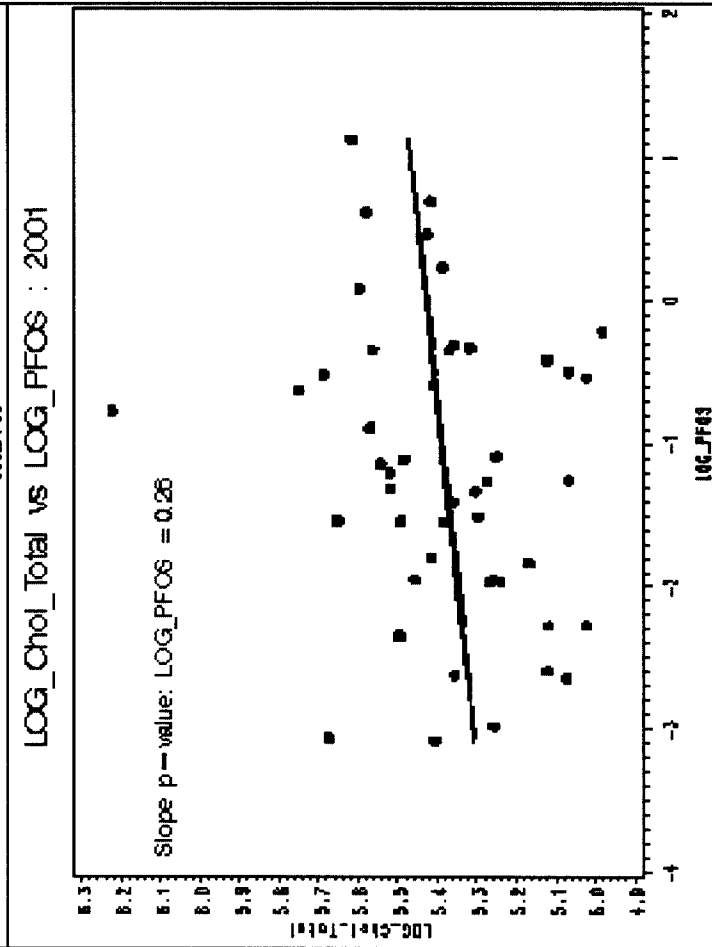
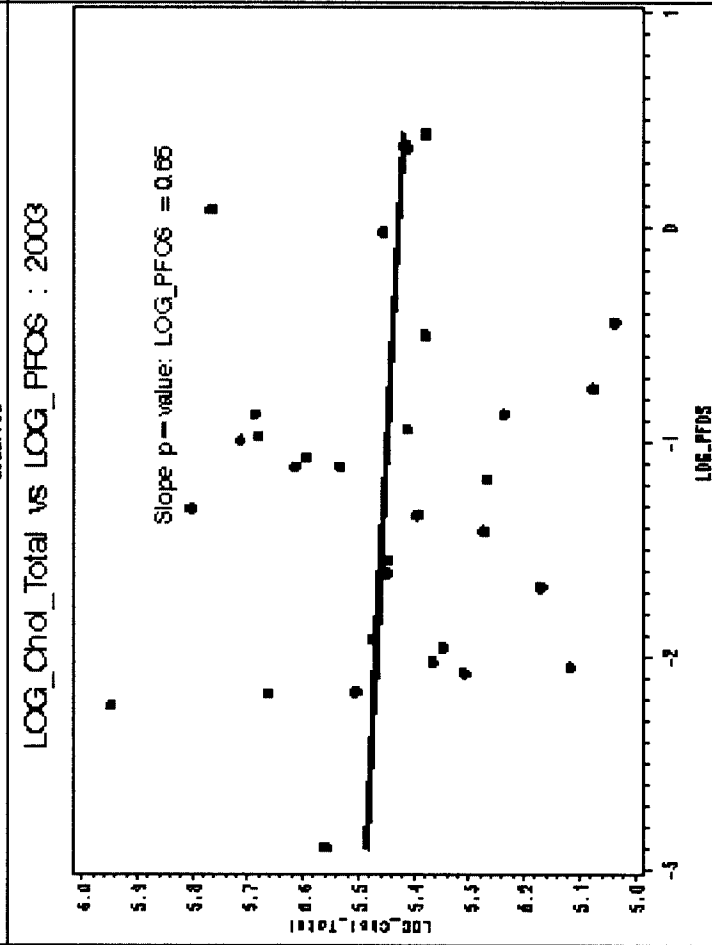
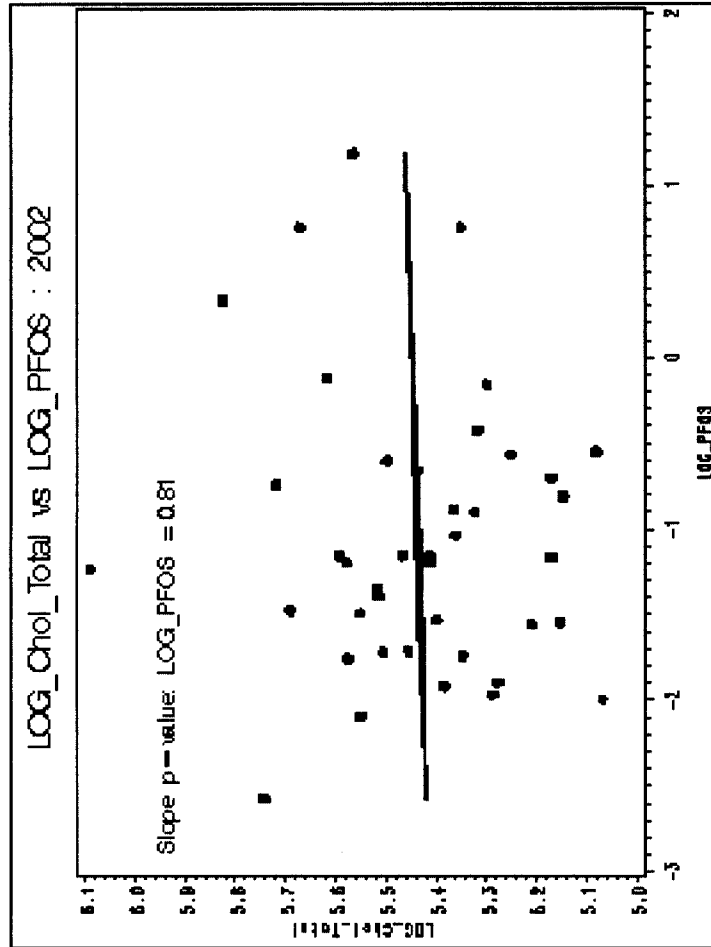
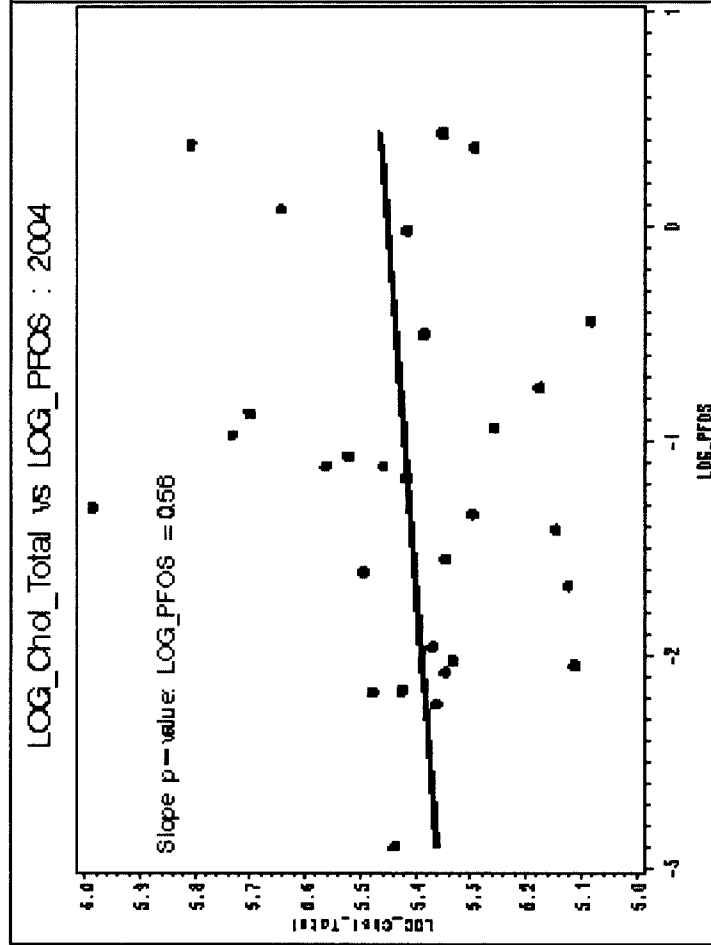


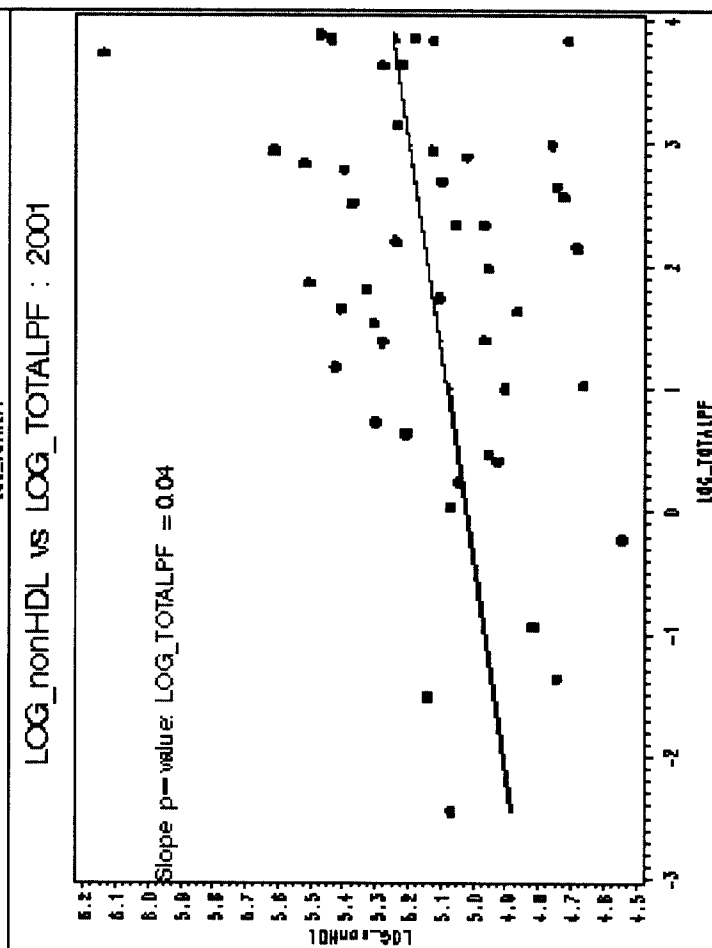
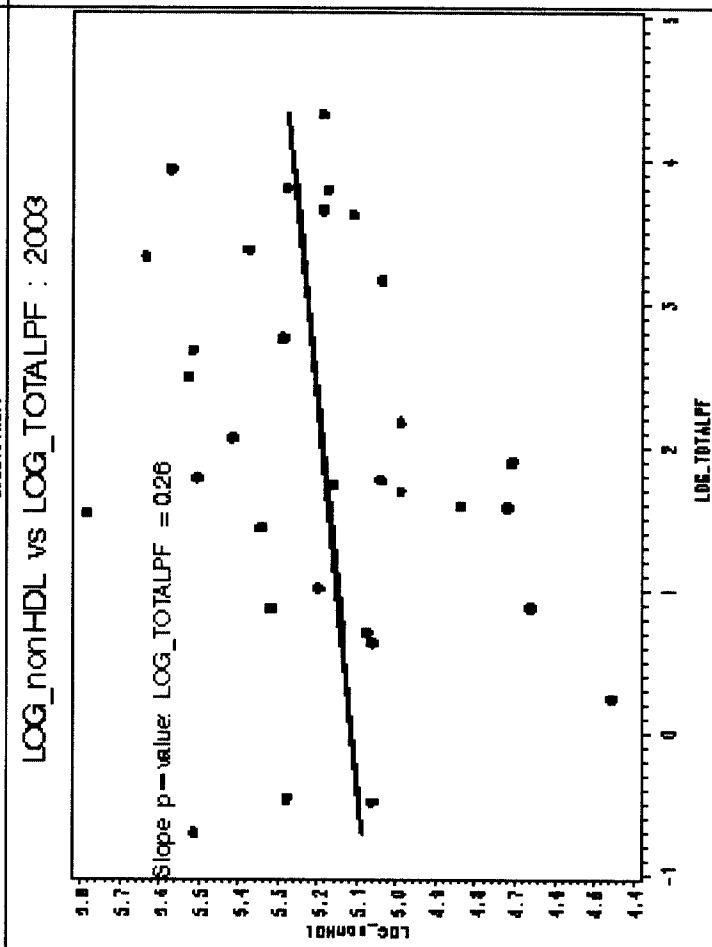
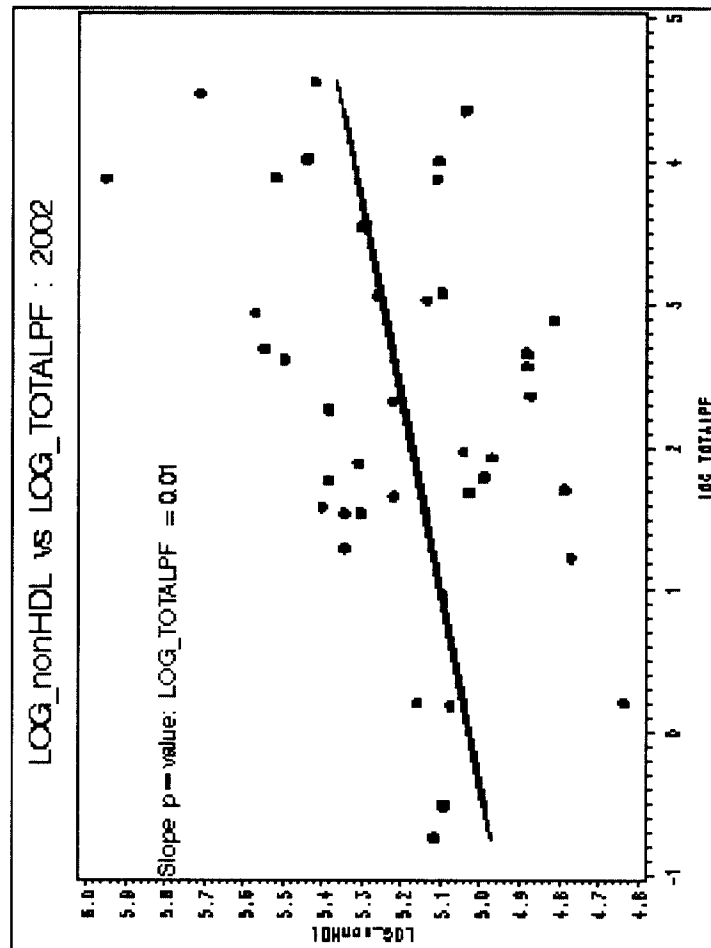
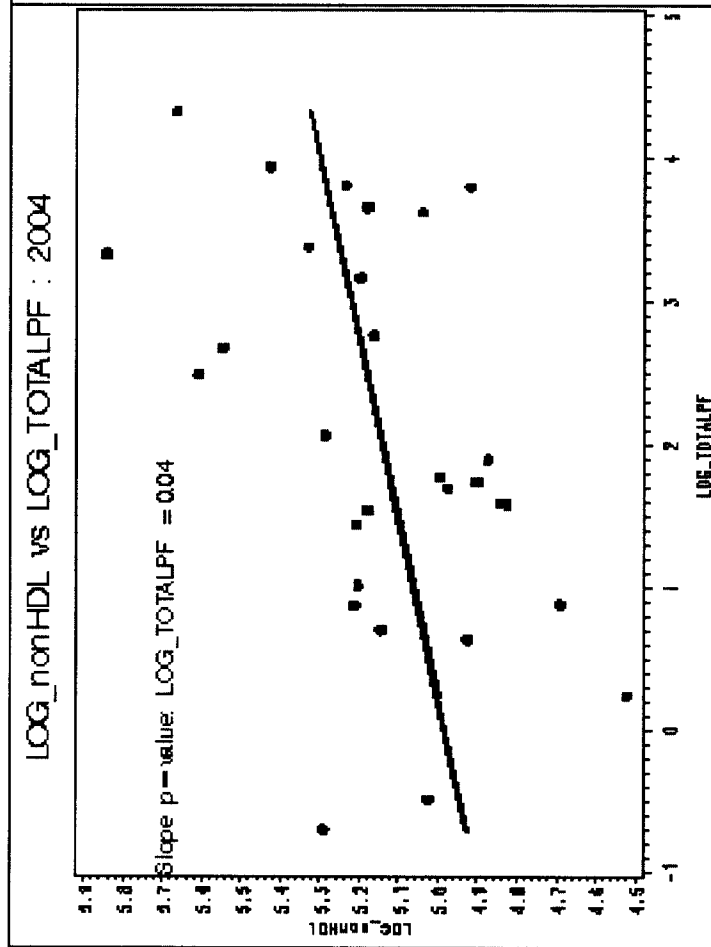
LOG_Chol_Total vs LOG_PFOA : 2003



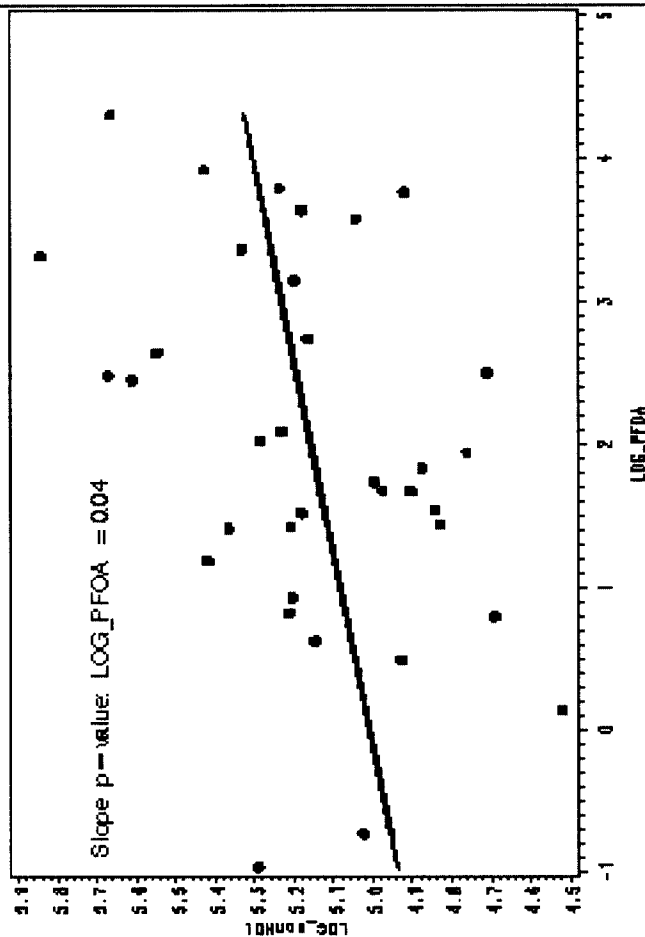
LOG_Chol_Total vs LOG_PFOA : 2001



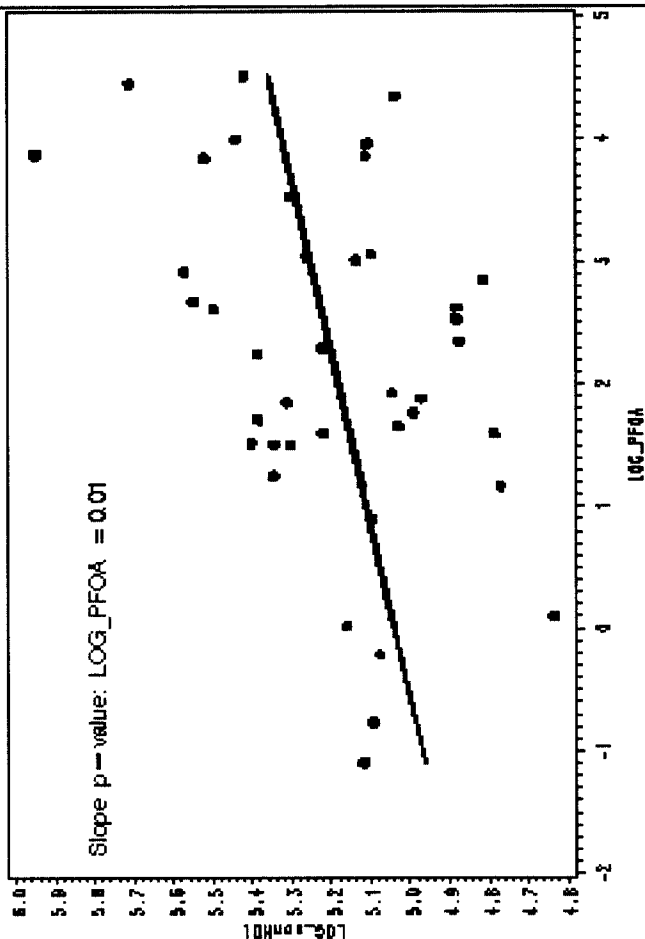




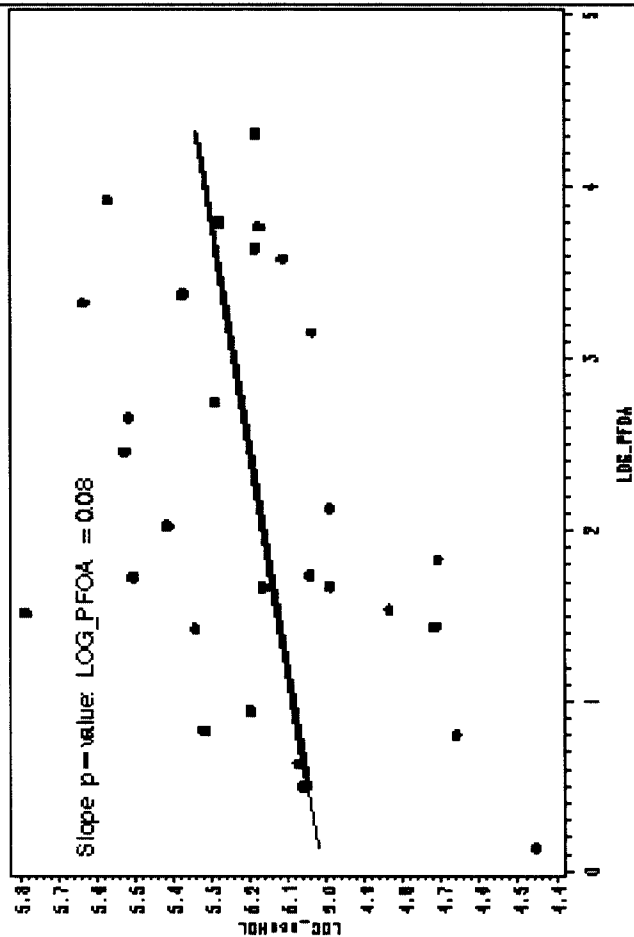
LOG_nonHDL vs LOG_PFOA : 2004



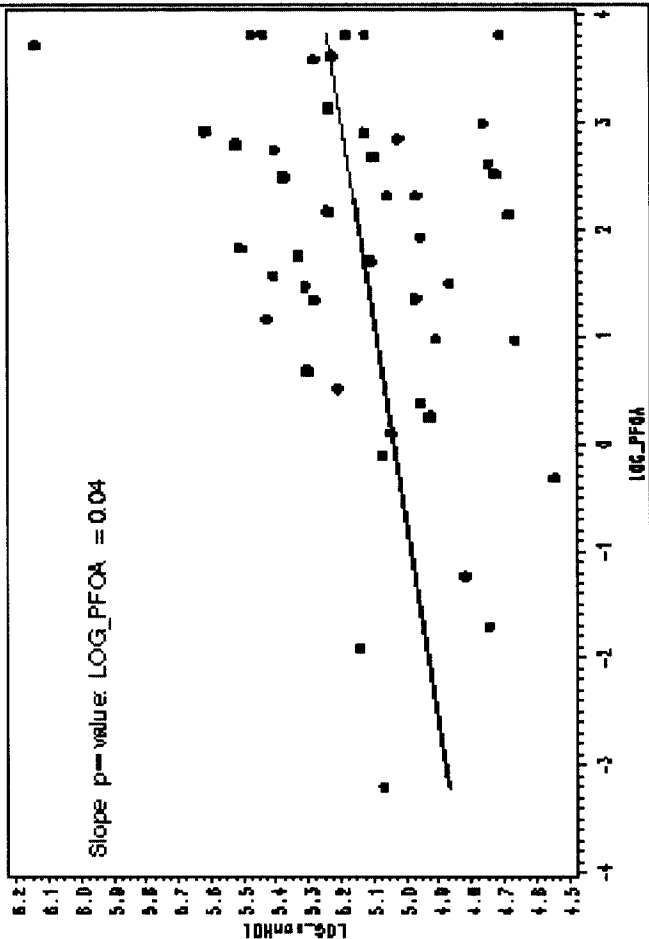
LOG_nonHDL vs LOG_PFOA : 2002



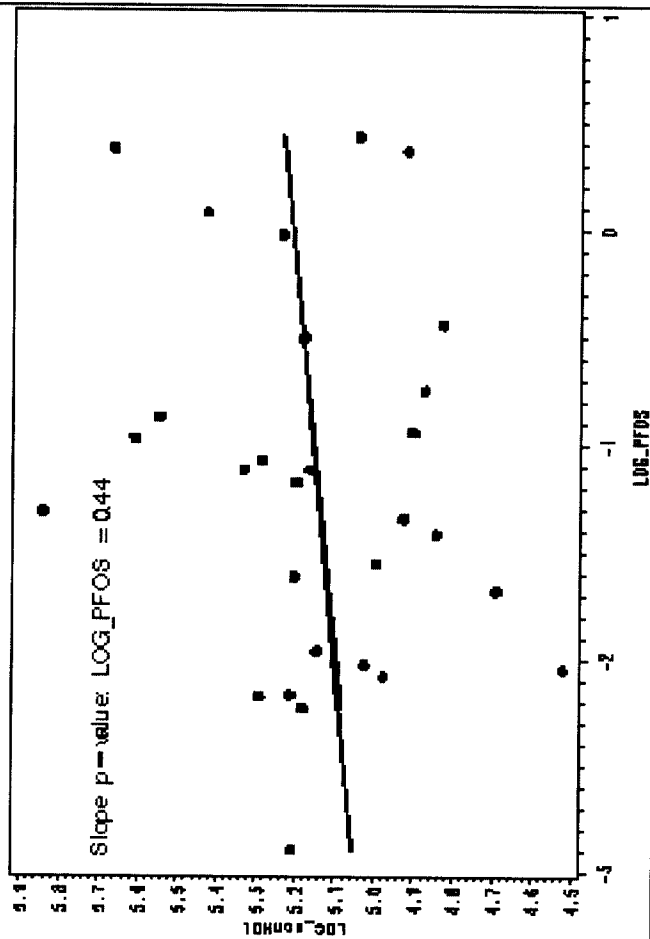
LOG_nonHDL vs LOG_PFOA : 2003
where (id_person >= 24 and id_person <= 32 and id_person <= 150)



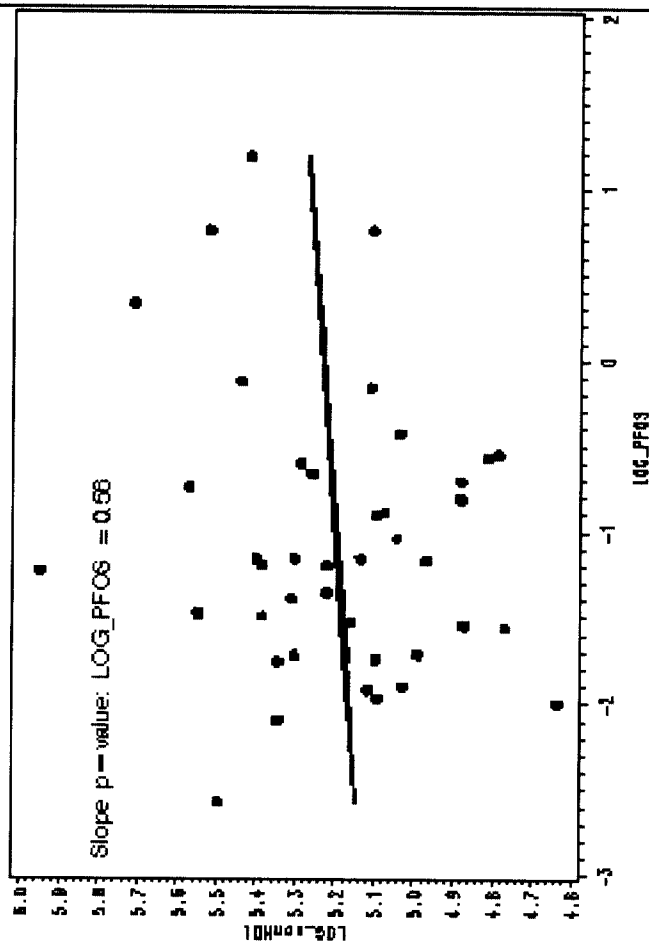
LOG_nonHDL vs LOG_PFOA : 2001



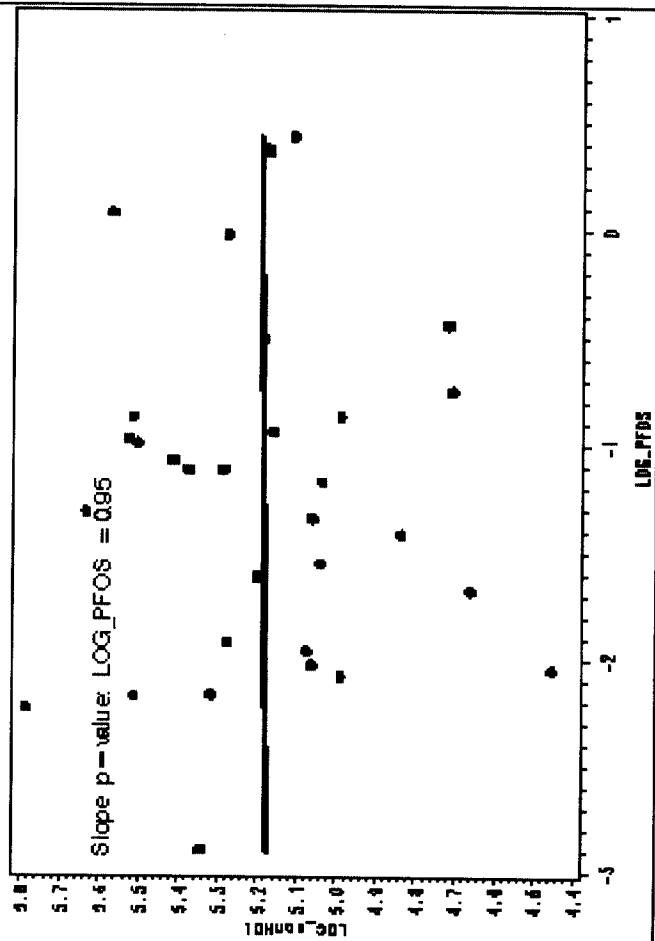
LOG_nonHDL vs LOG_PFO8 : 2004



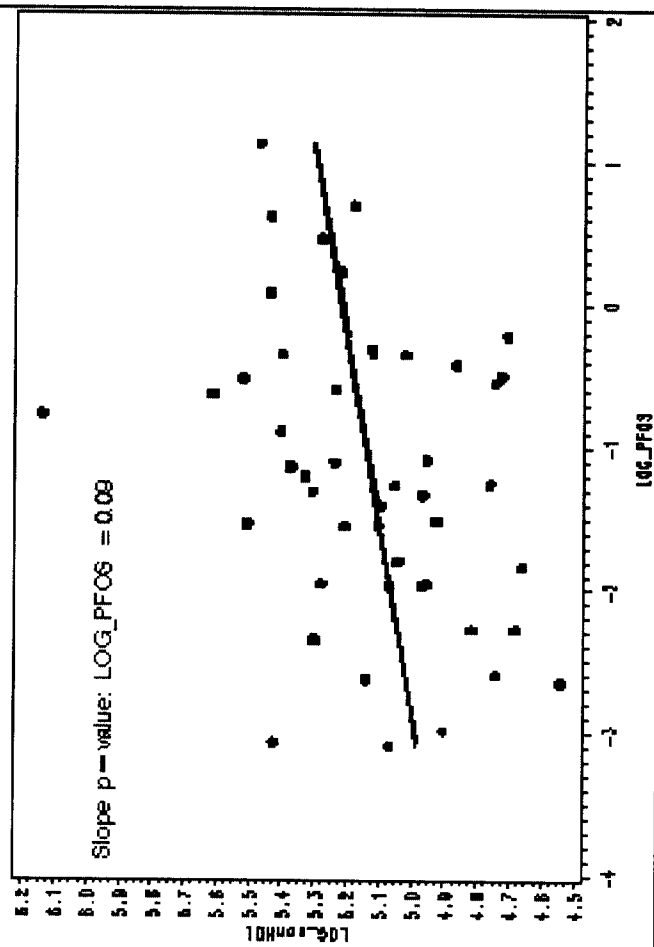
LOG_nonHDL vs LOG_PFO8 : 2002

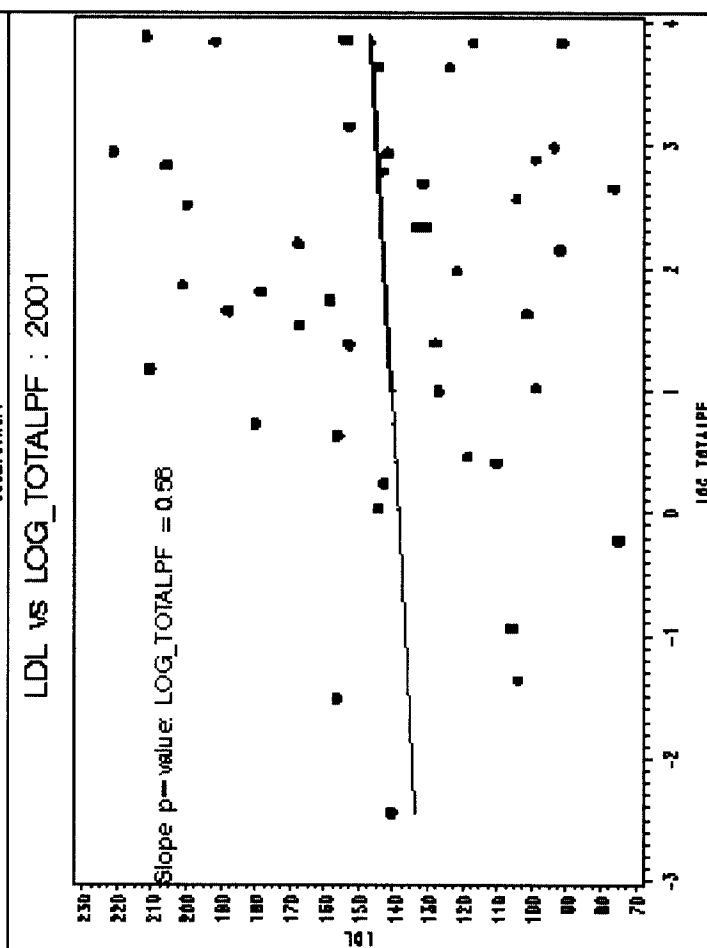
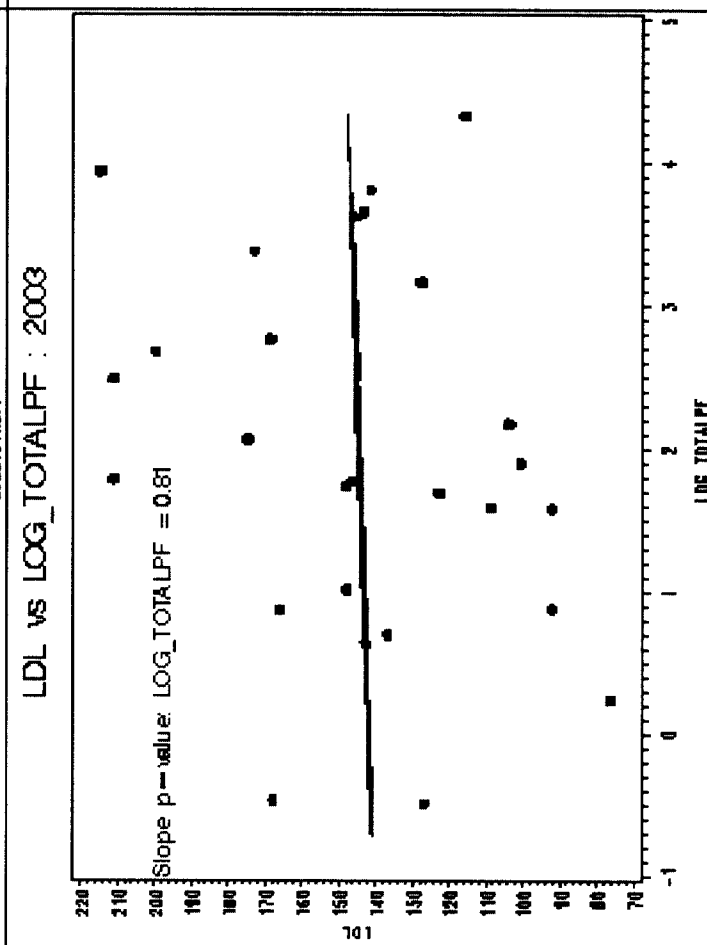
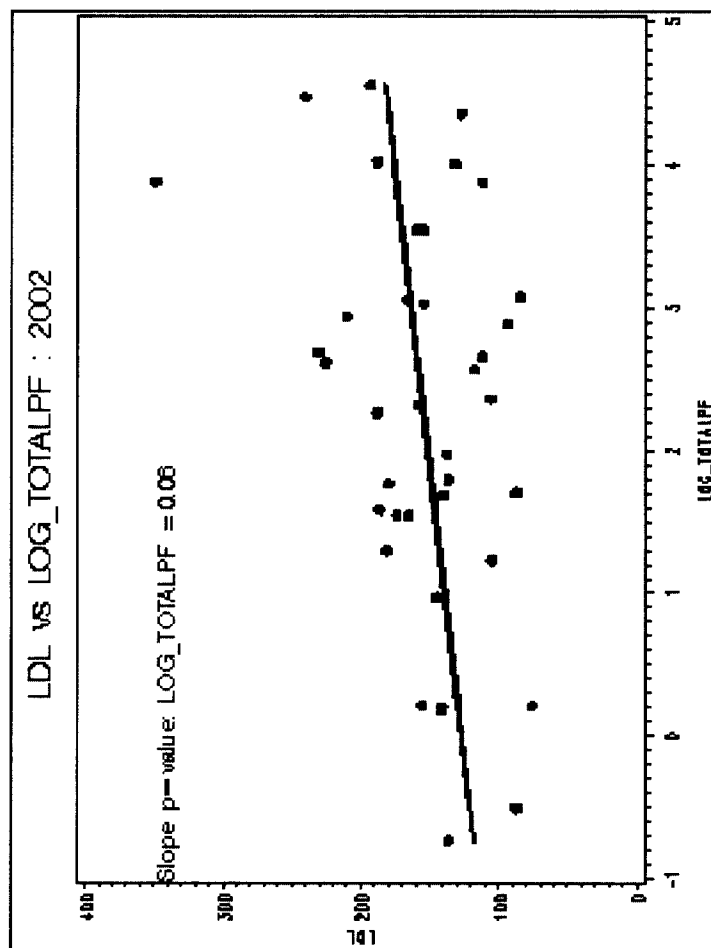
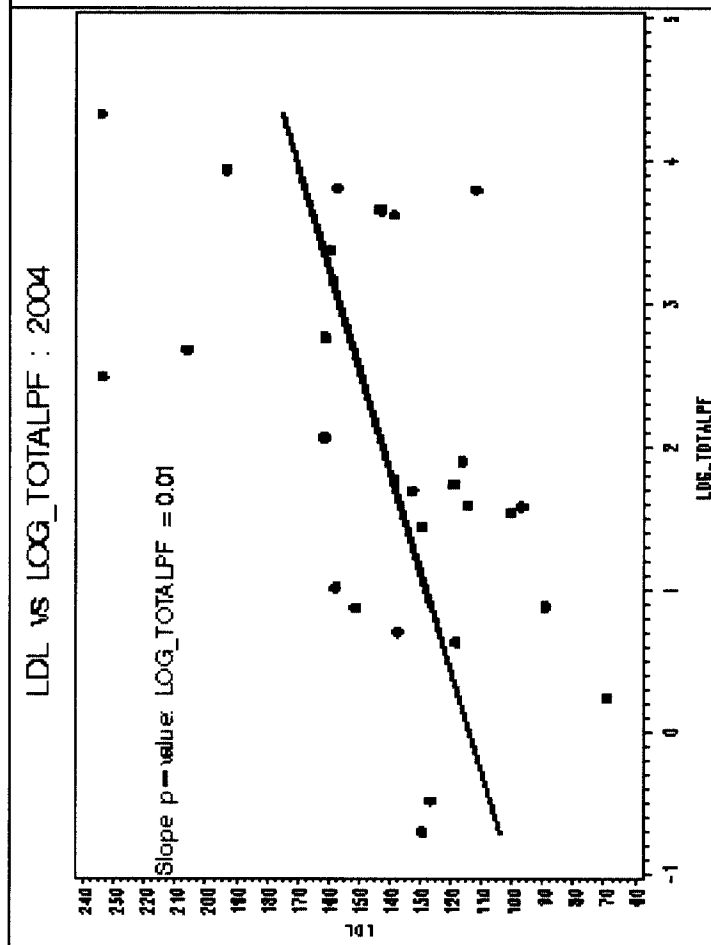


LOG_nonHDL vs LOG_PFO8 : 2003

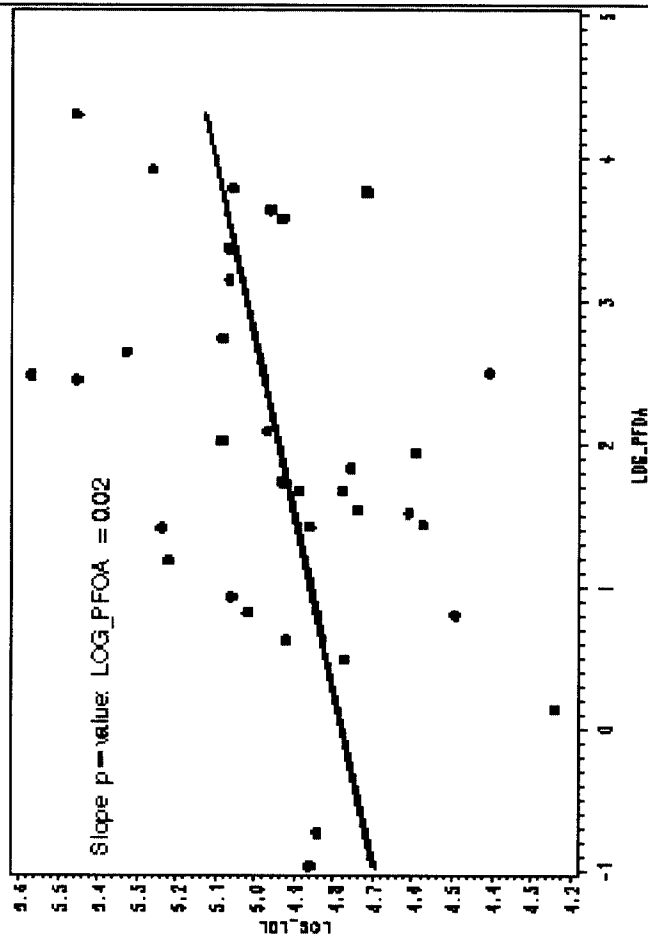


LOG_nonHDL vs LOG_PFO8 : 2001

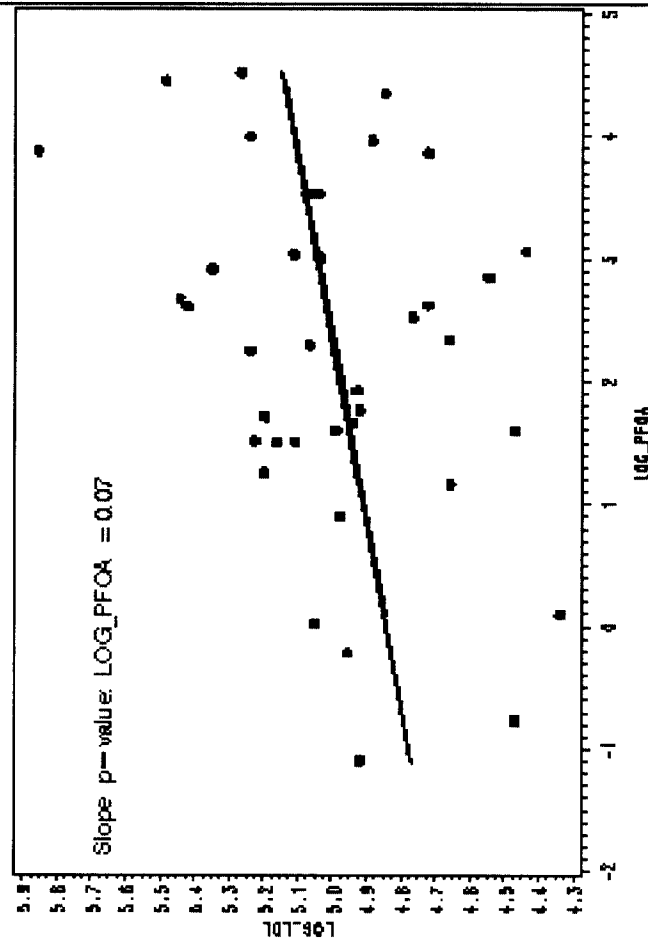




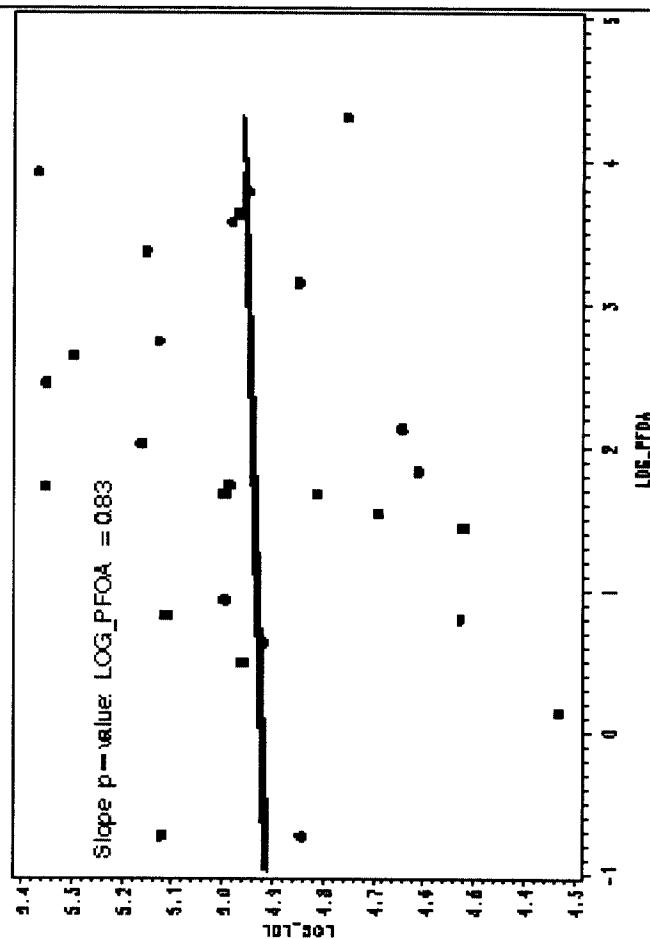
LOG_LDL vs LOG_PFOA : 2004



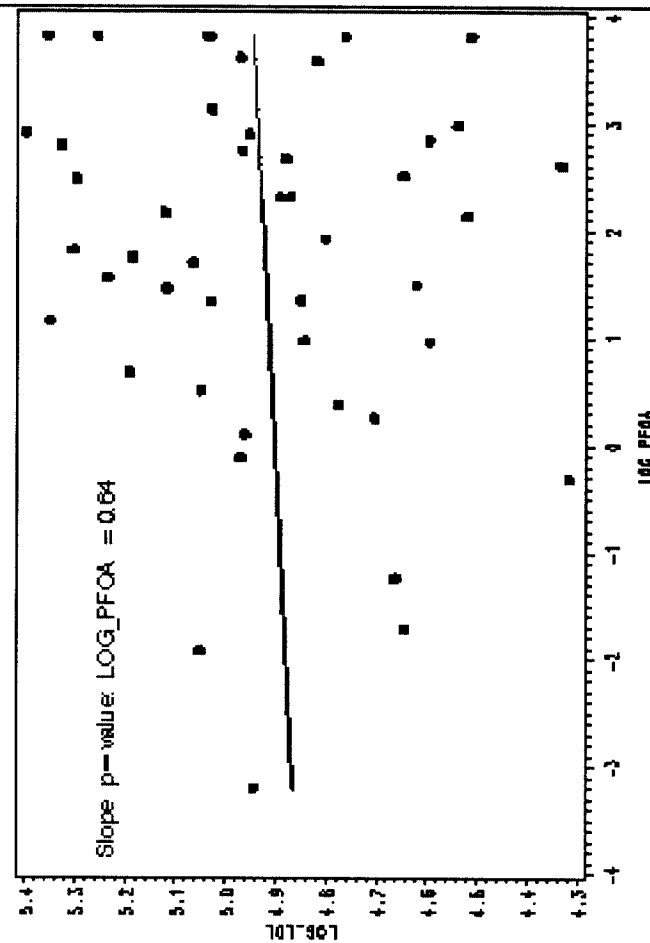
LOG_LDL vs LOG_PFOA : 2002

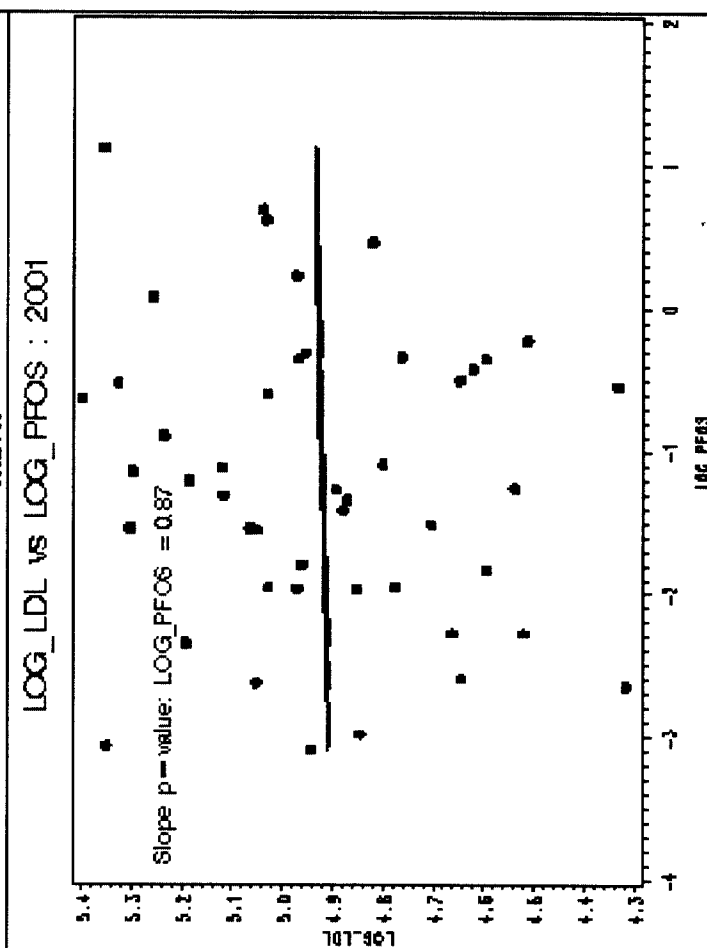
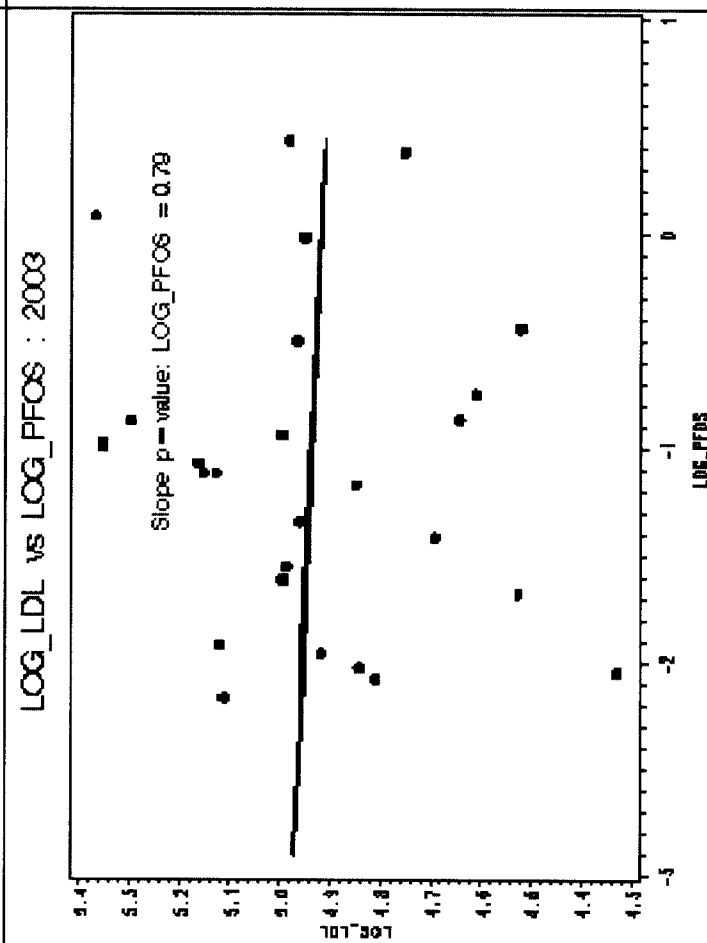
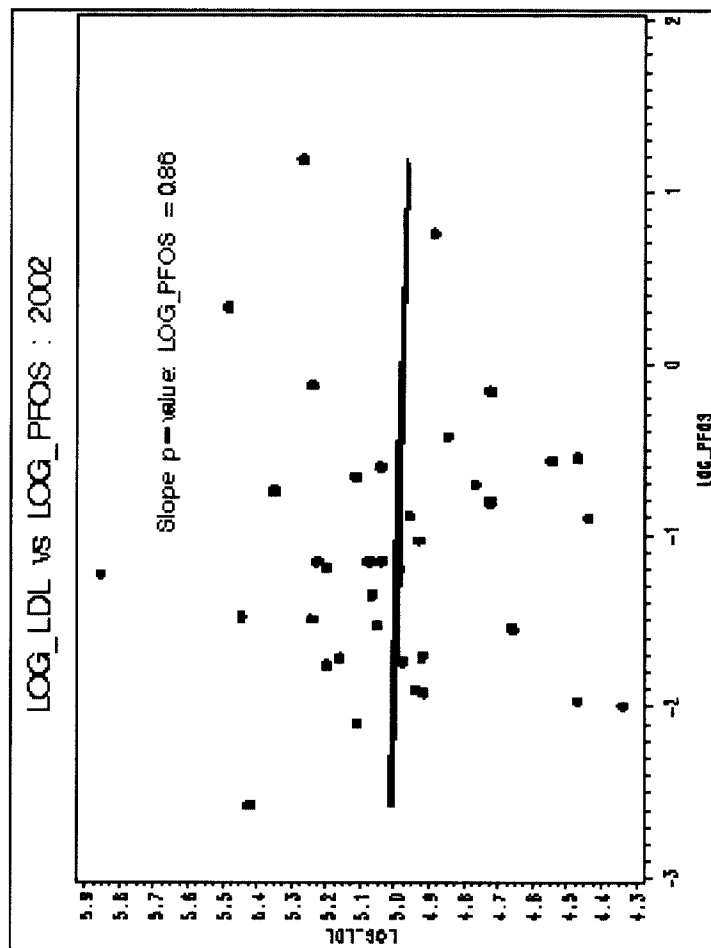
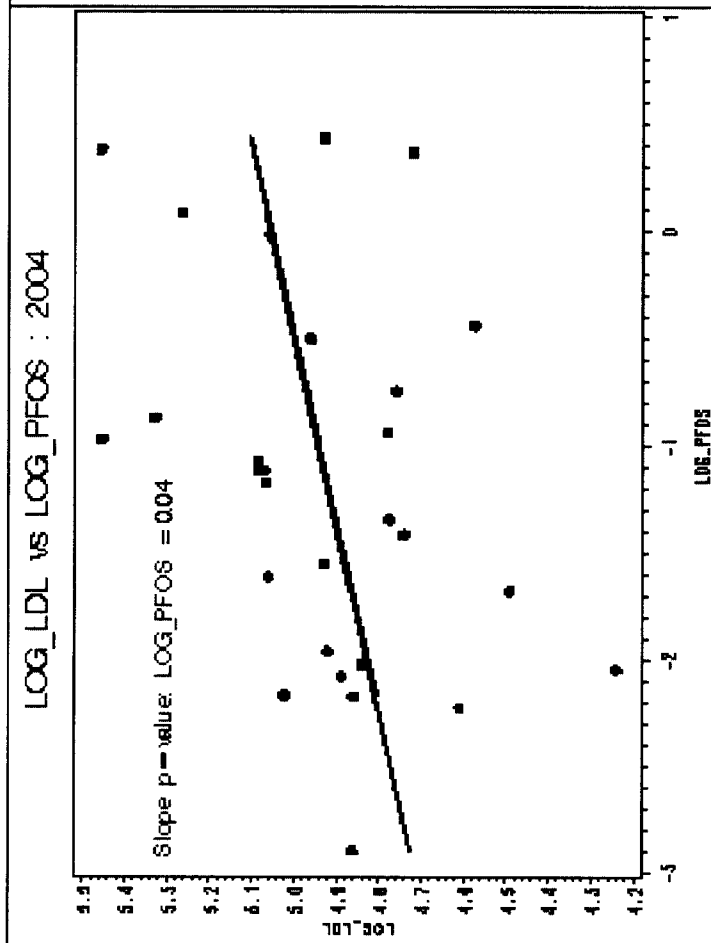


LOG_LDL vs LOG_PFOA : 2003

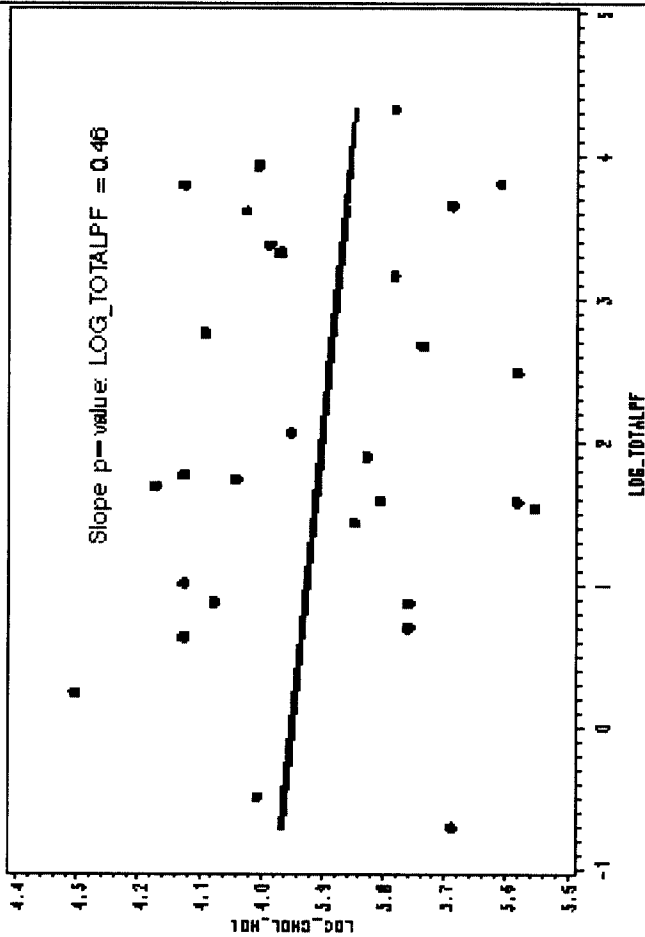


LOG_LDL vs LOG_PFOA : 2001

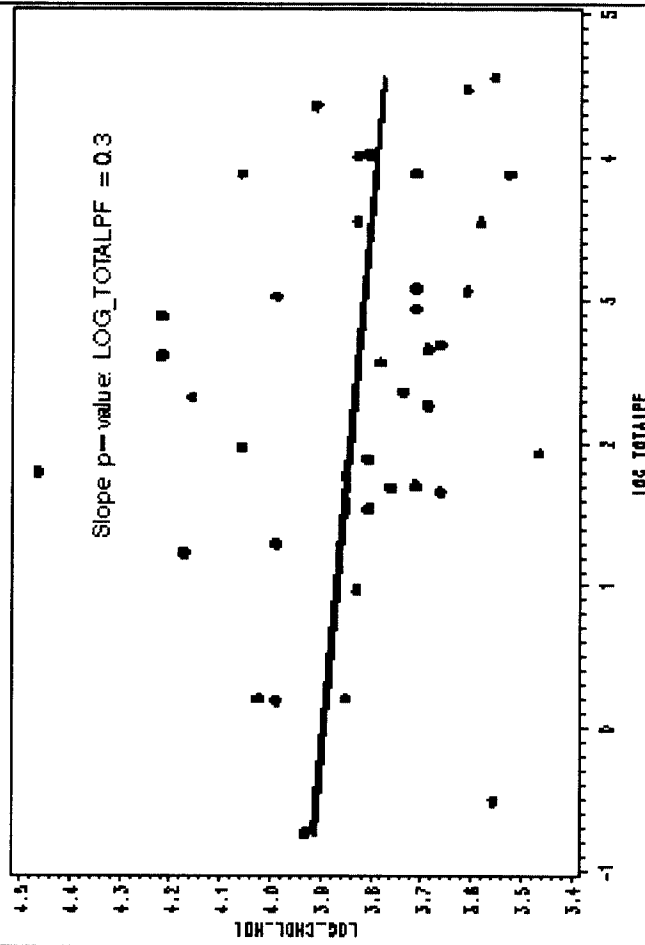




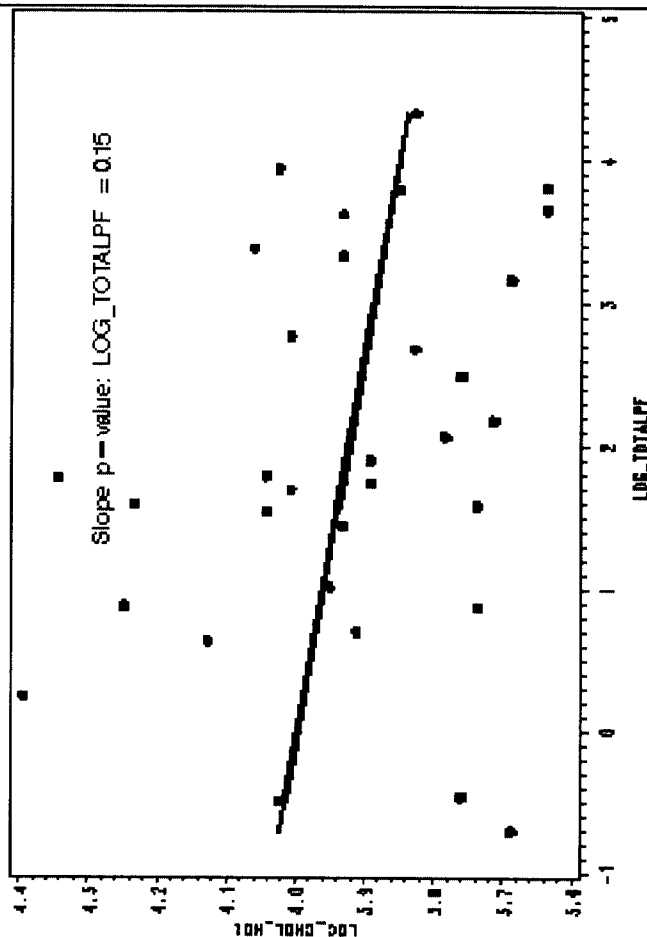
LOG_CHOL_HDL vs LOG_TOTALPF : 2004



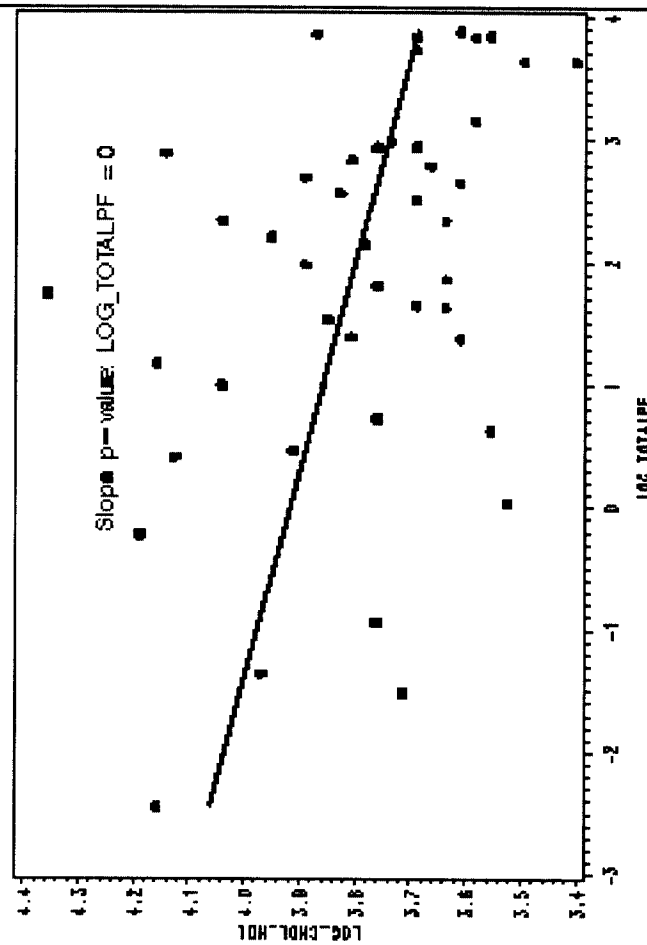
LOG_CHOL_HDL vs LOG_TOTALPF : 2002



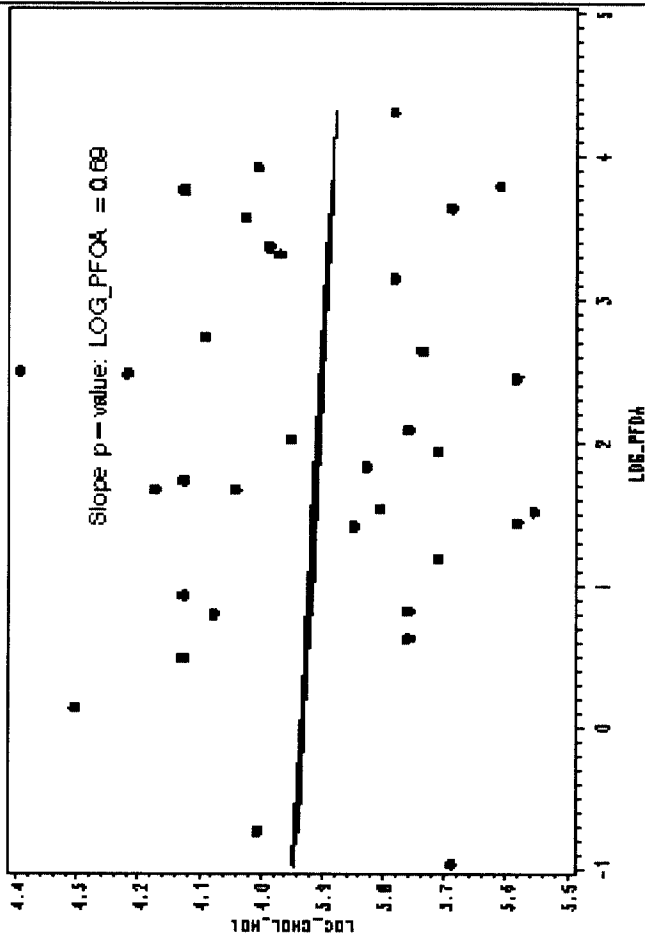
LOG_CHOL_HDL vs LOG_TOTALPF : 2003



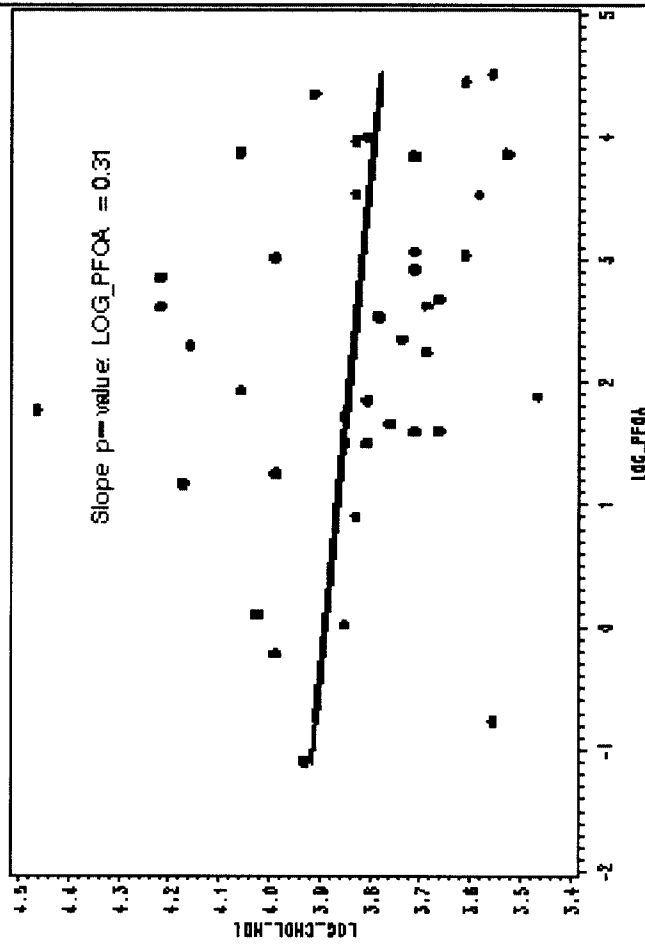
LOG_CHOL_HDL vs LOG_TOTALPF : 2001



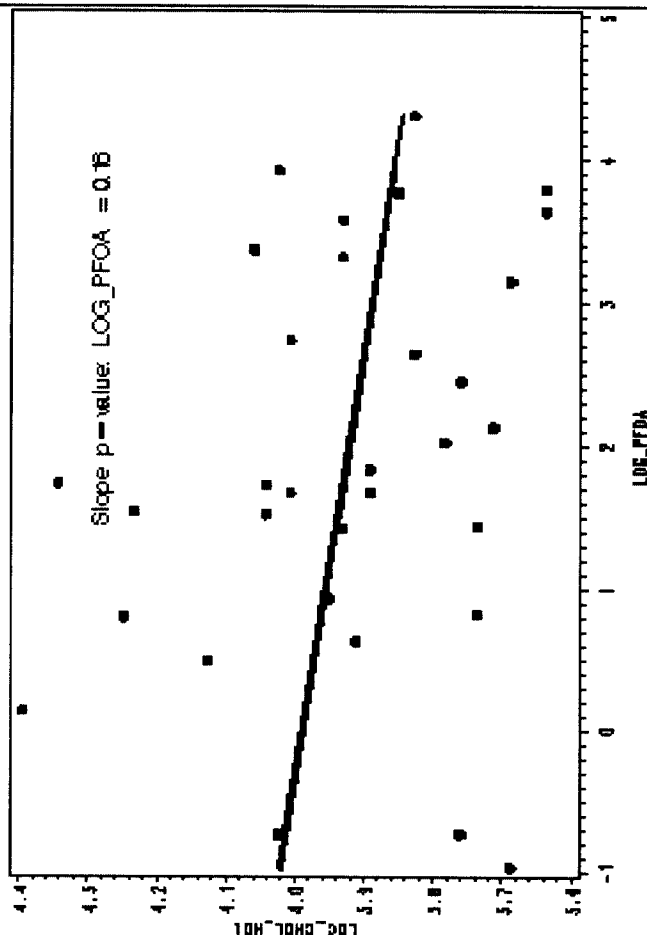
LOG_CHOL_HDL vs LOG_PFOA : 2004



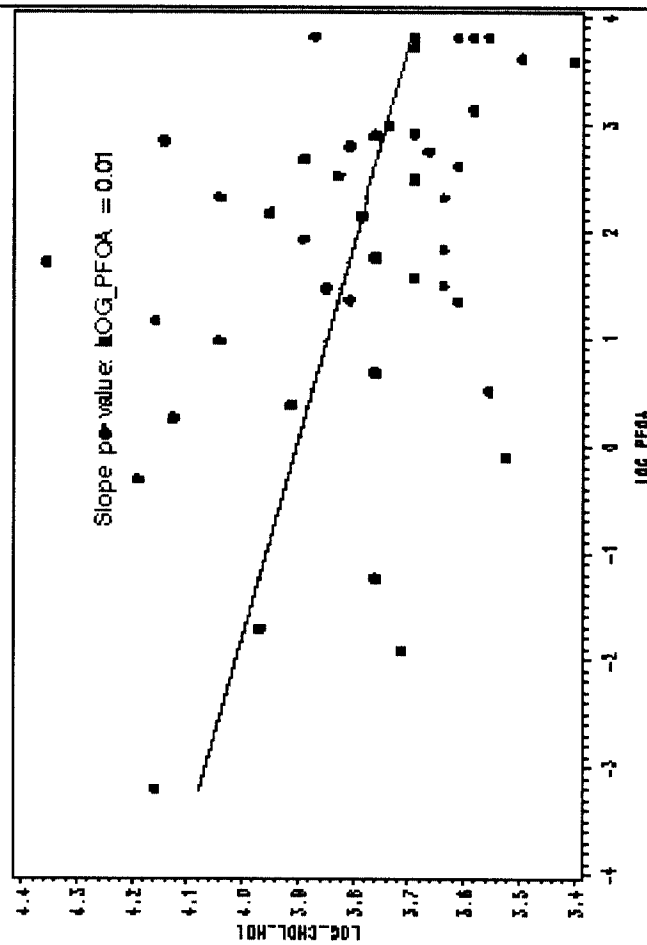
LOG_CHOL_HDL vs LOG_PFOA : 2002



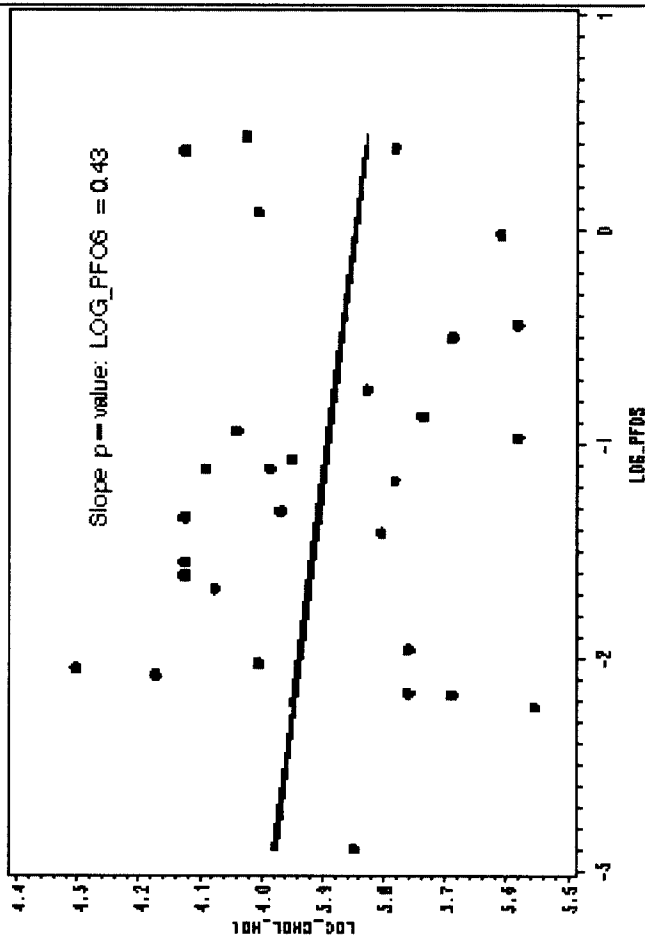
LOG_CHOL_HDL vs LOG_PFOA : 2003



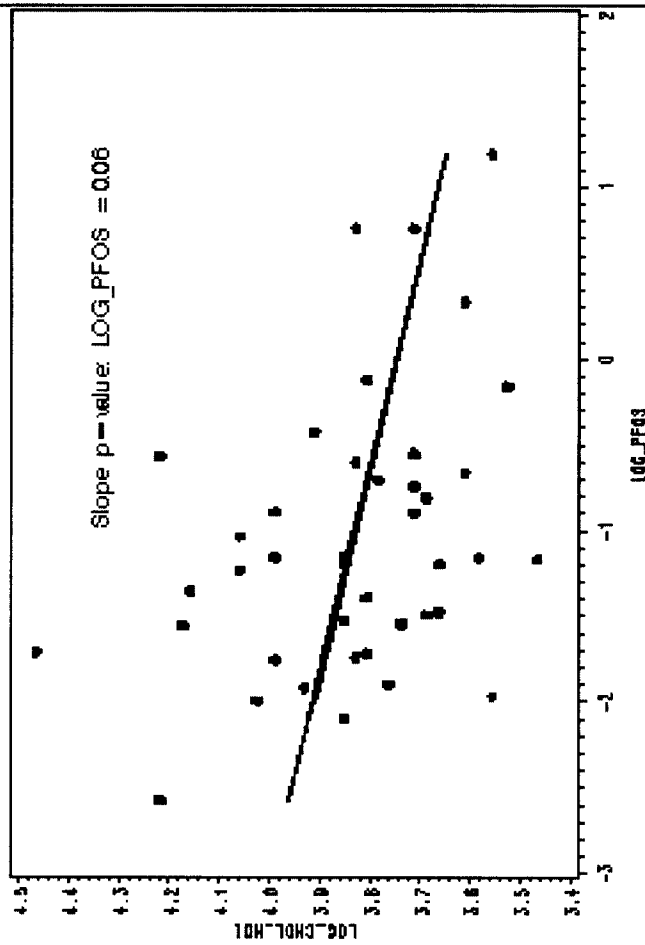
LOG_CHOL_HDL vs LOG_PFOA : 2001



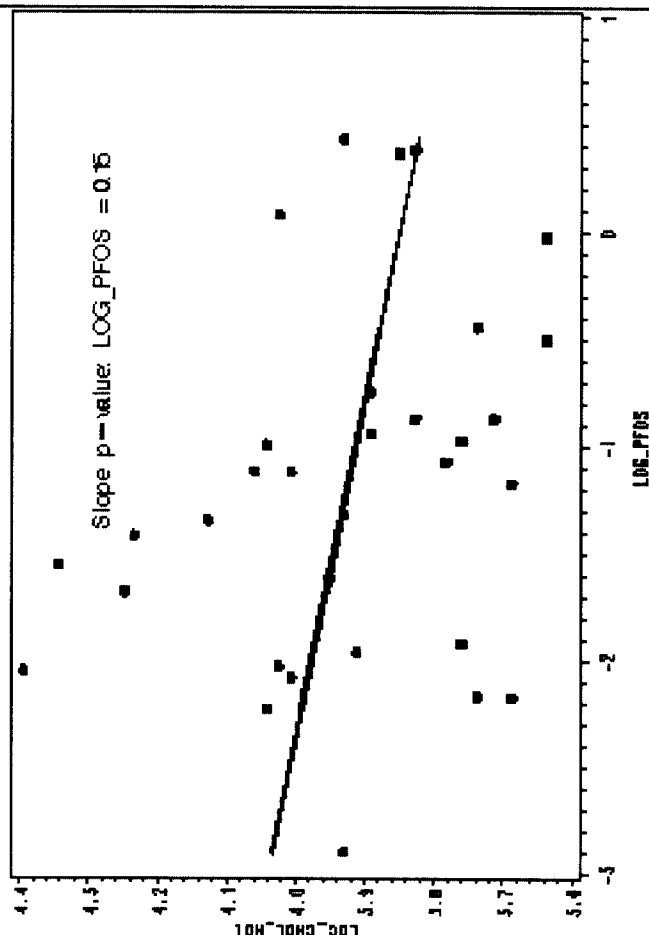
LOG_CHOL_HDL vs LOG_PFO6 : 2004



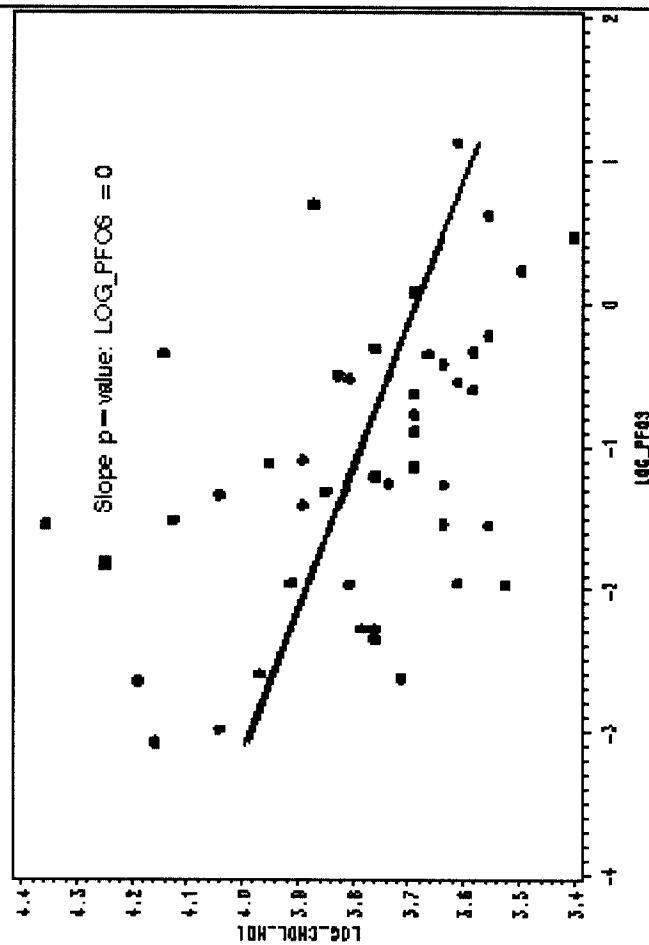
LOG_CHOL_HDL vs LOG_PFO6 : 2002

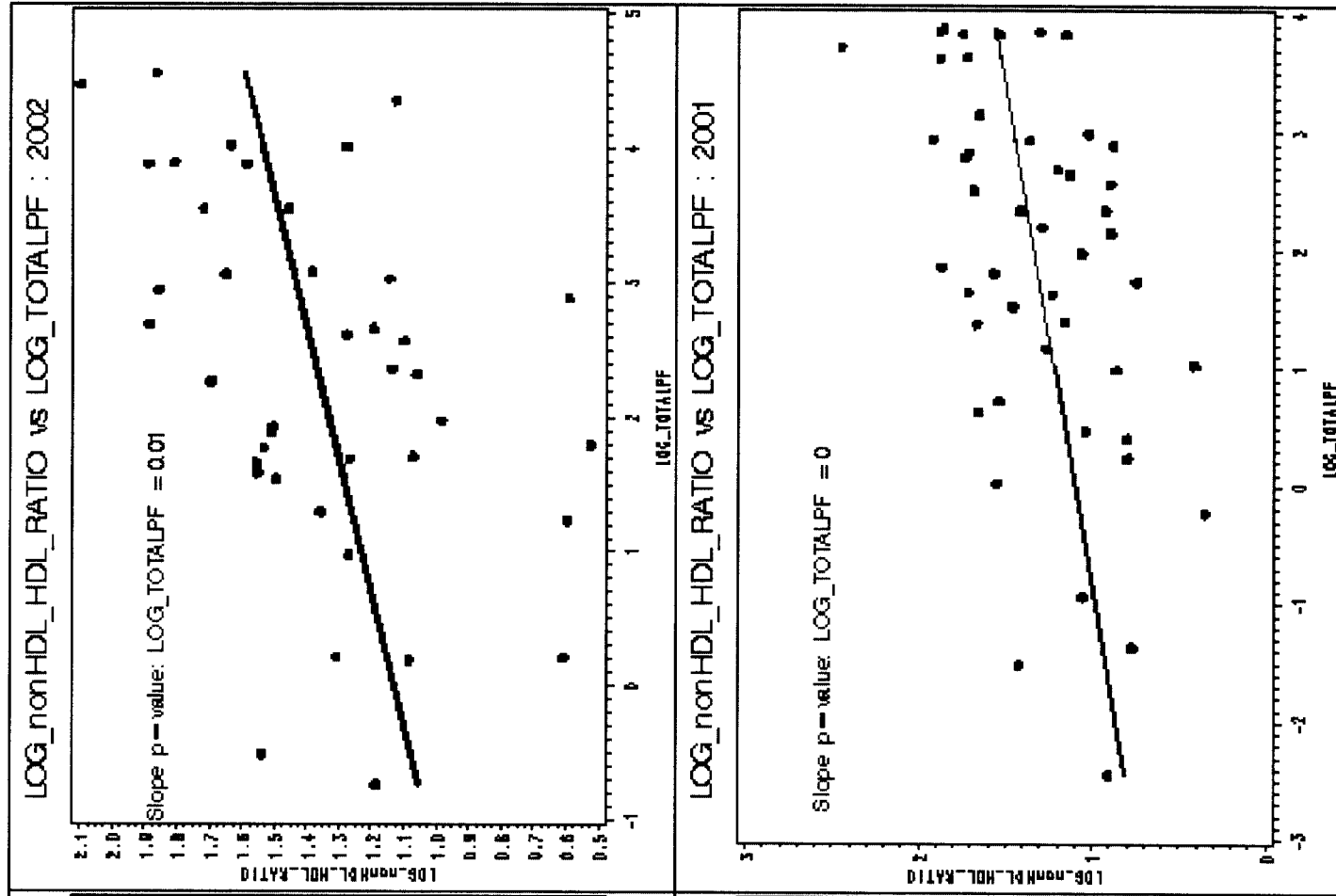
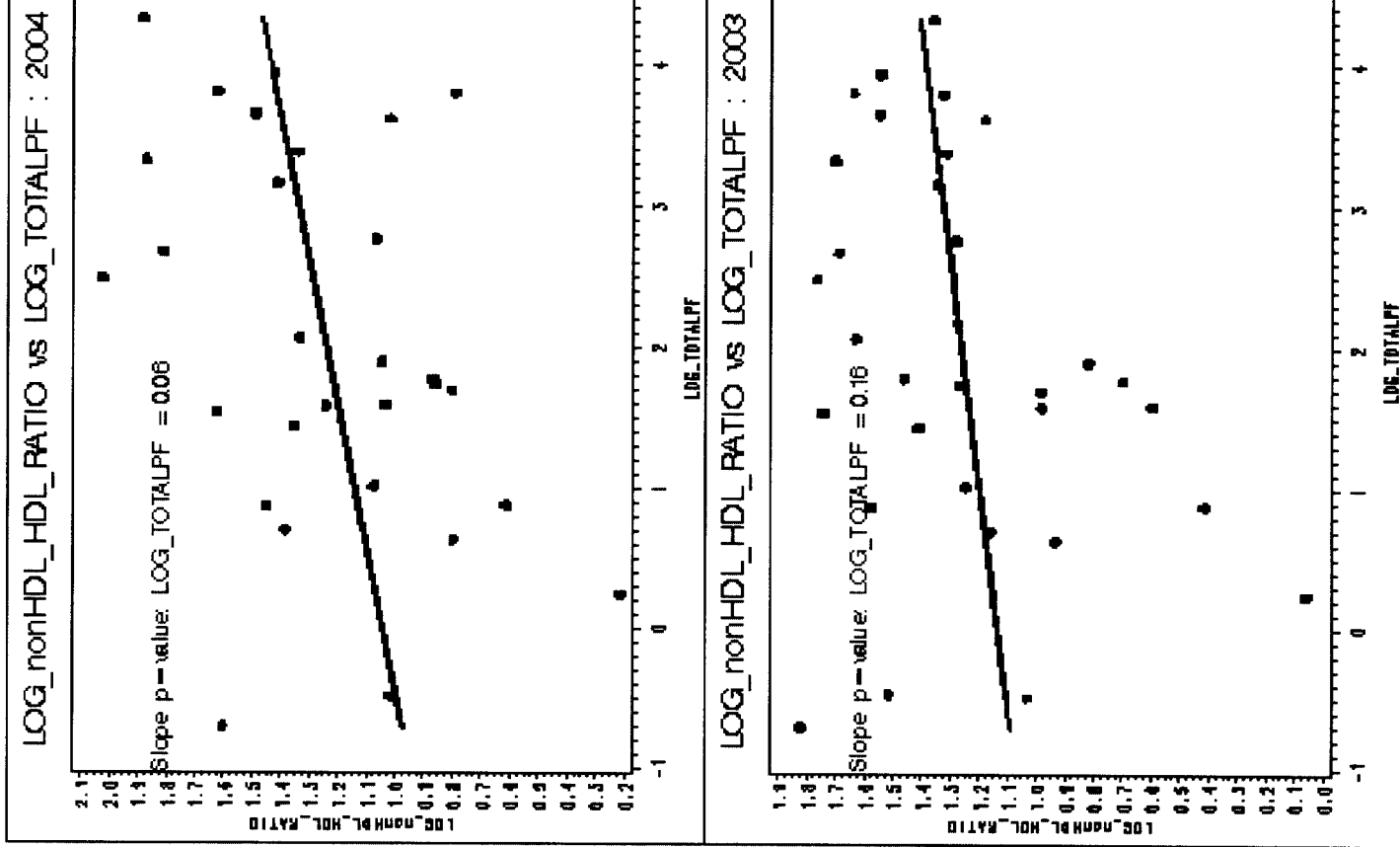


LOG_CHOL_HDL vs LOG_PFO6 : 2003

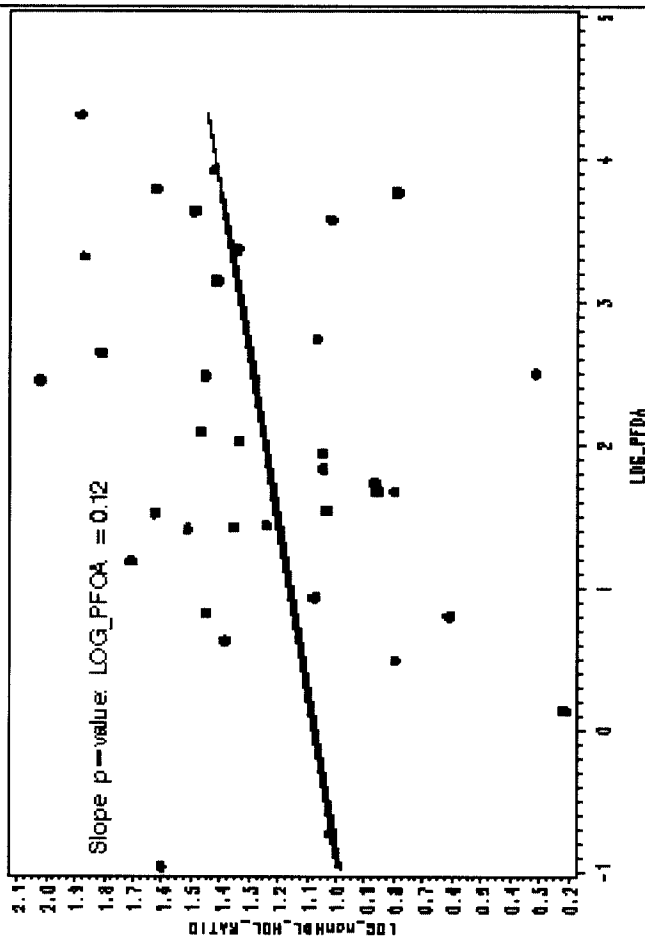


LOG_CHOL_HDL vs LOG_PFO6 : 2001

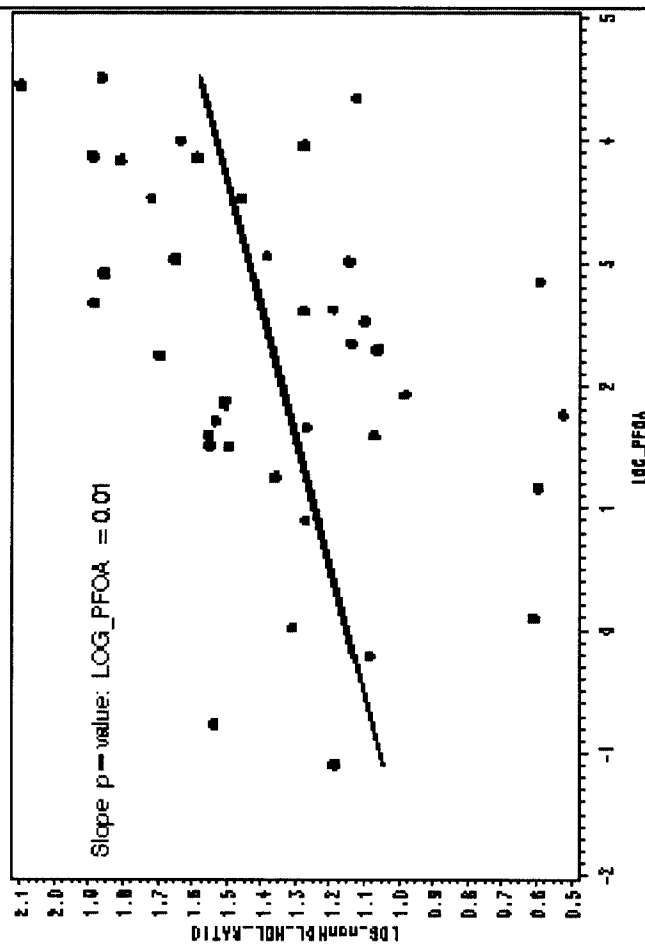




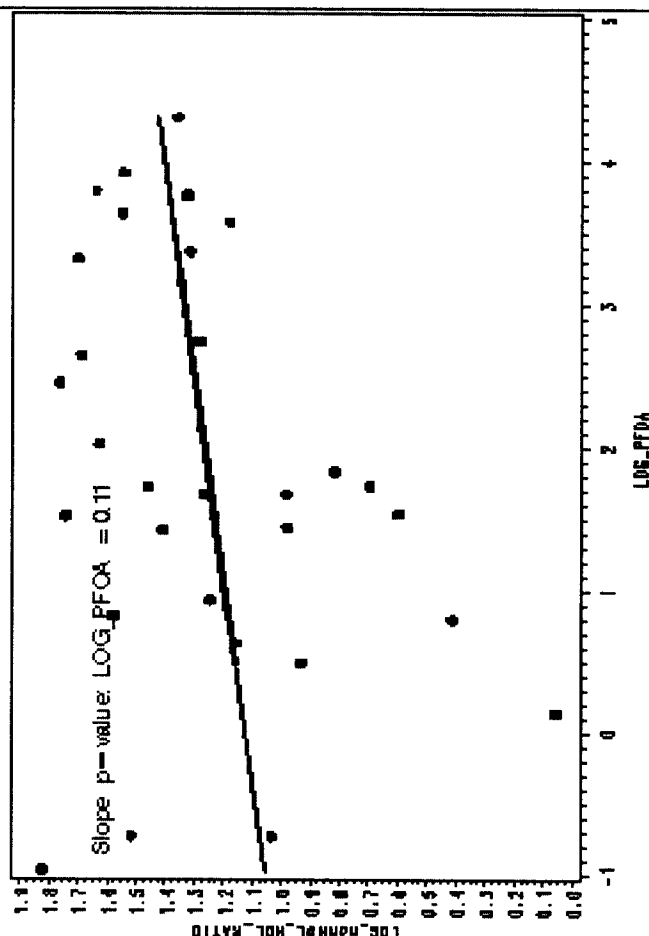
LOG_nonHDL_HDL_RATIO vs LOG_PFOA : 2004



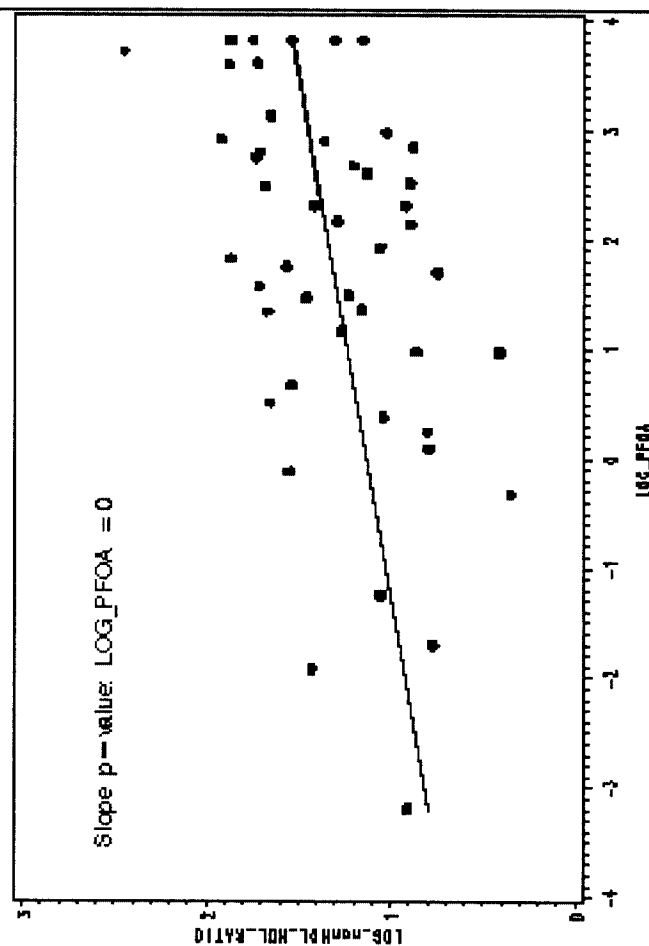
LOG_nonHDL_HDL_RATIO vs LOG_PFOA : 2002



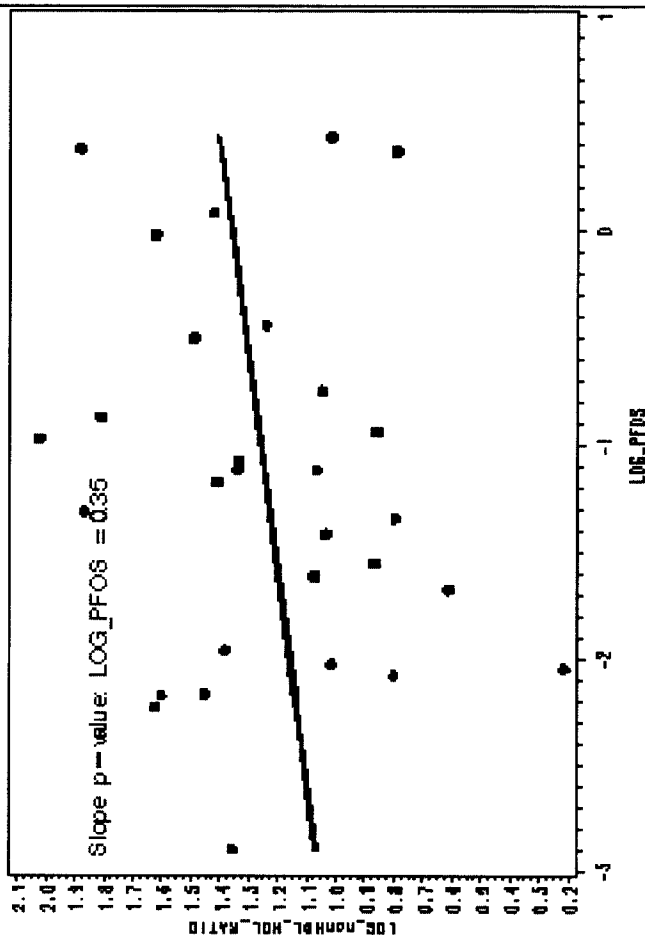
LOG_nonHDL_HDL_RATIO vs LOG_PFOA : 2003



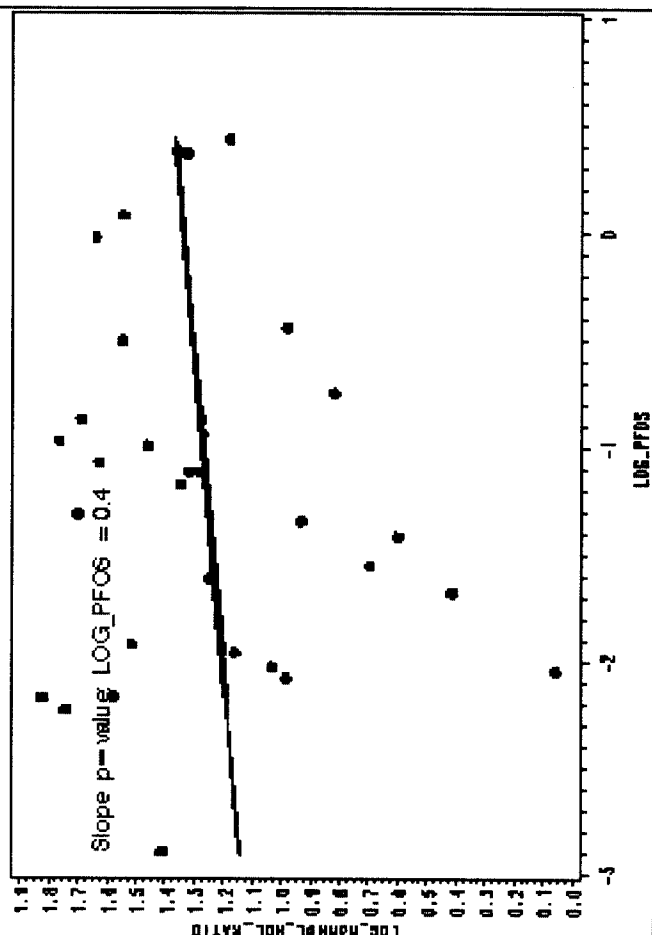
LOG_nonHDL_HDL_RATIO vs LOG_PFOA : 2001



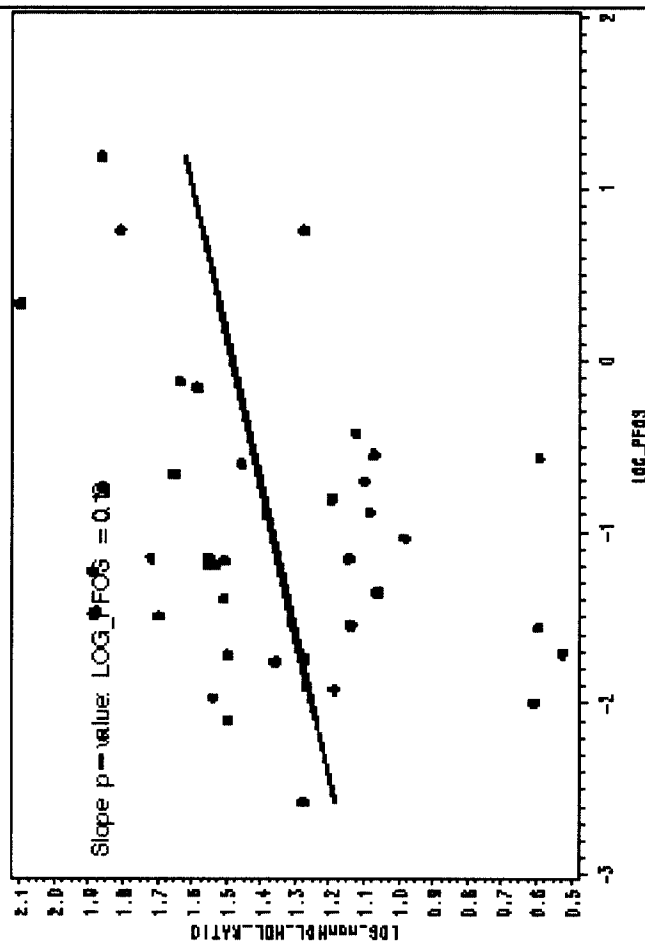
LOG_nonHDL_HDL_RATIO vs LOG_PFO8 : 2004



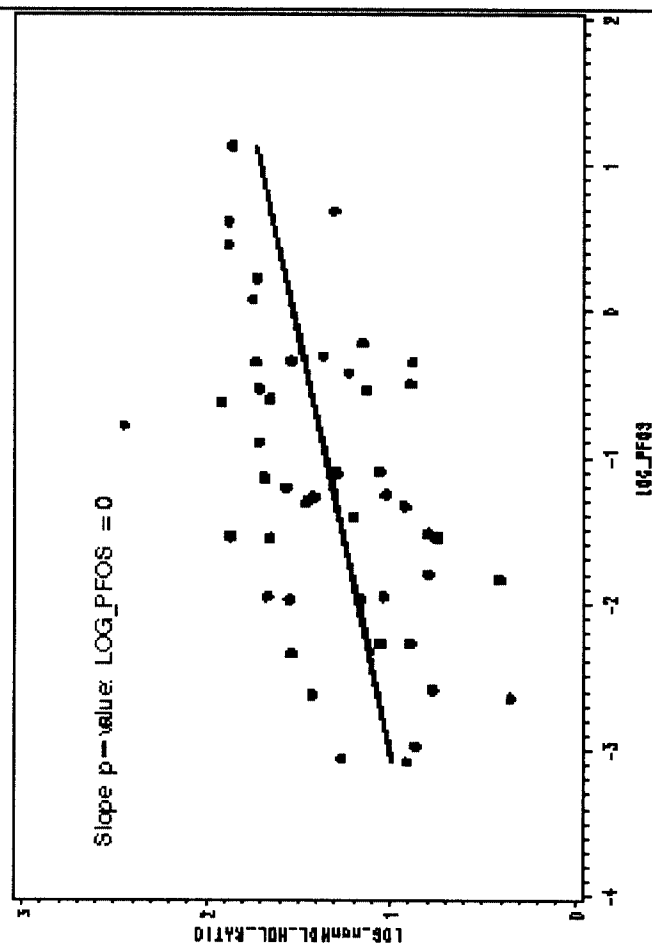
LOG_nonHDL_HDL_RATIO vs LOG_PFO8 : 2003



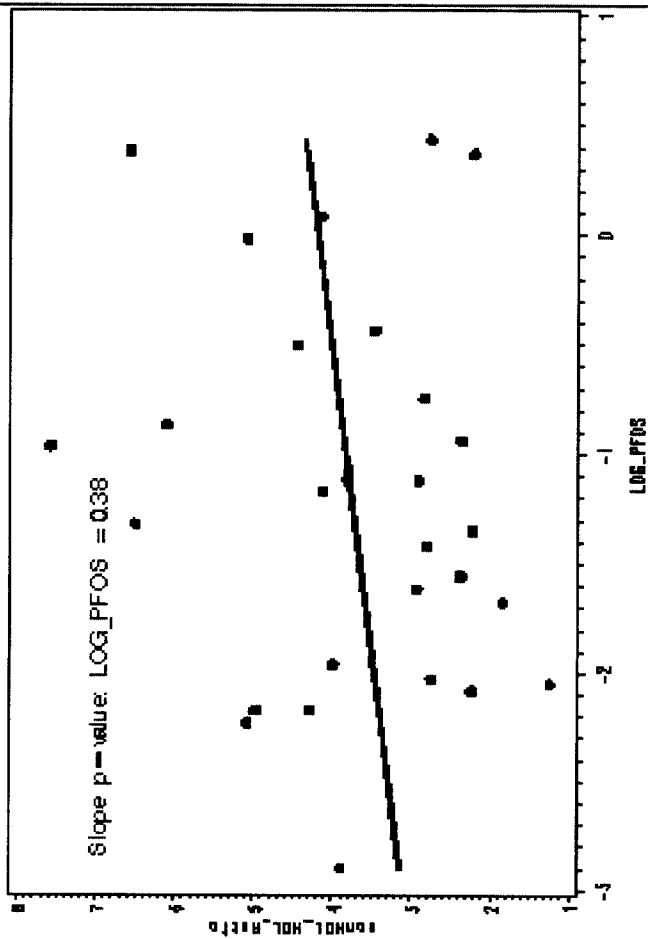
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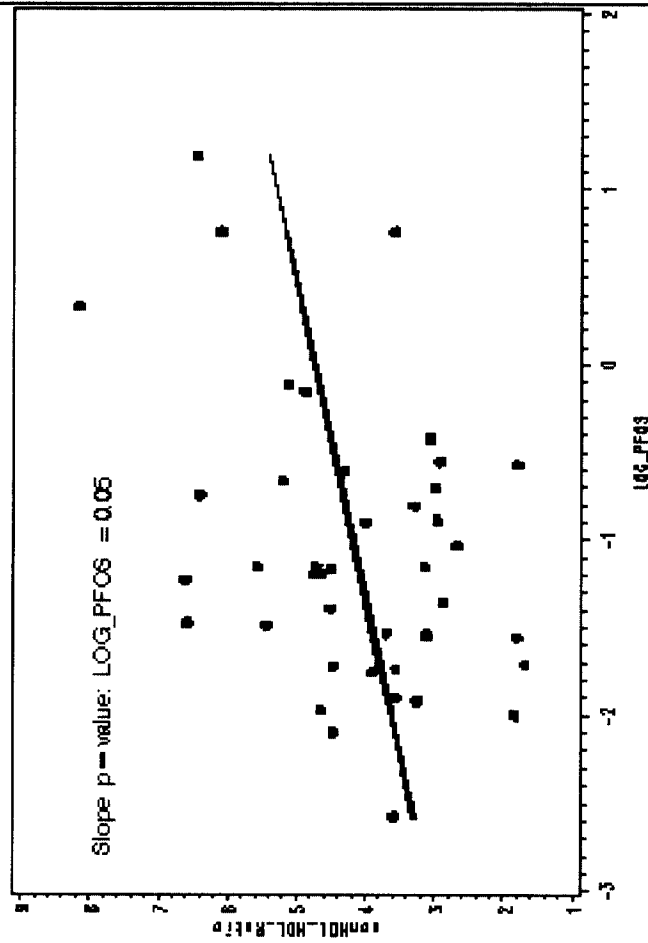
LOG_nonHDL_HDL_RATIO vs LOG_PFO8 : 2001



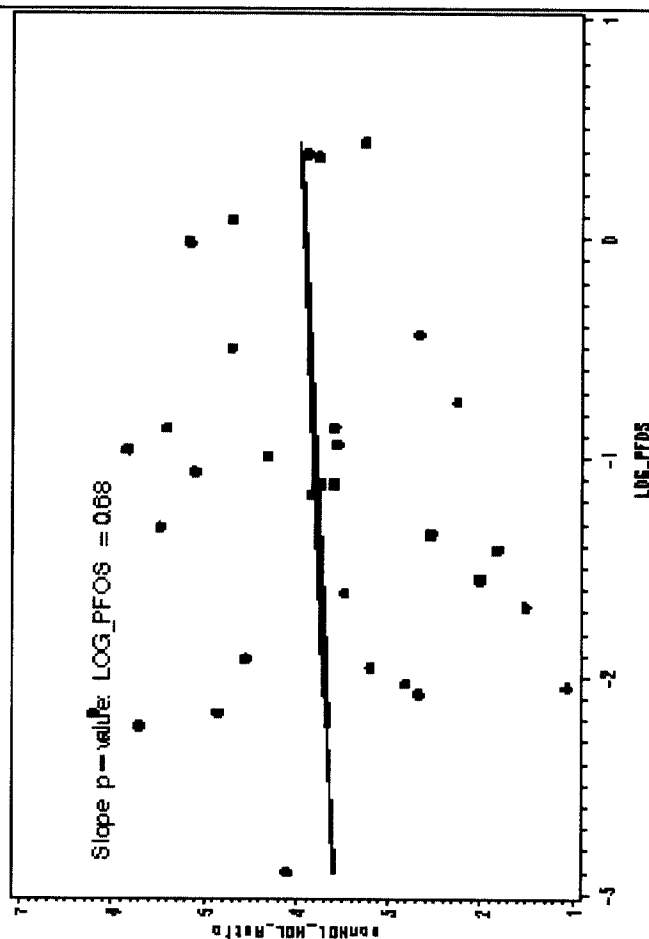
nonHDL_HDL_RATIO vs LOG_PFO5 : 2004



nonHDL_HDL_RATIO vs LOG_PFO5 : 2002



nonHDL_HDL_RATIO vs LOG_PFO5 : 2003



nonHDL_HDL_RATIO vs LOG_PFO5 : 2001

